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PARLIAMENTARY DEBATES
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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

Tuesday 12 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 in the Chamber and 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 moment, I will adjourn the House immediately. 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.

Animal Welfare and Wildlife Crime Offences

Question

12.07 pm

Asked by ***Baroness Hayman of Ullock***

To ask Her Majesty's Government what plans they have to improve enforcement rates for (1) animal welfare, and (2) wildlife crime, offences.

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]: My Lords, the Government recognise the importance of tackling wildlife crime and animal cruelty. Since 2016, Defra and the Home Office have jointly committed £300,000 a year to funding the National Wildlife Crime Unit. We have also ensured that legislation contains the necessary powers for enforcement agencies to investigate any possible offences and bring offenders to justice. The enforcement of wildlife and animal welfare laws are operational matters for the police and local authorities.

Baroness Hayman of Ullock (Lab) [V]: The Animal Welfare (Sentencing) Bill is important legislation with cross-party support, but it appears to be stuck. Is there a date for Committee stage and, if not, why not? On breaking the Hunting Act, particularly in light of the Hunting Office webinars now being investigated, does the Minister accept that enforcement will remain difficult until action is taken to strengthen the law and stop trail hunting being used as a cover for illegal hunting?

Lord Goldsmith of Richmond Park (Con) [V]: The Government support increasing the maximum custodial sentence for animal cruelty offences from six months to five years. We have always been clear about that. It will enable courts to take a much firmer approach to cases such as dog fighting, abuse of puppies and kittens, gross neglect of farm animals and so on. The Animal Welfare (Sentencing) Bill, which the noble Baroness mentions, was introduced into the House of Commons by Chris Loder MP and completed Second Reading on 23 October. We are currently awaiting a date for Committee. The Government have been clear that we will continue to support it as it makes its way through Parliament. We are committed to ensuring that it becomes law.

The offences that the noble Baroness cited are already offences under the Hunting Act; they are already illegal, so the issue is one of enforcement. She is right to raise them, as some troubling exposés have been made available to us but, again, crimes have been committed and it is down to the authorities to ensure that those responsible face the full force of the law.

Baroness Fookes (Con) [V]: My Lords, what steps are the Government taking to encourage the enforcement of international law in relation to wild animals? Is the Minister aware that a species called the pangolin, fully protected in theory, is being hunted in great numbers, according to that excellent organisation, the Born Free Foundation?

Lord Goldsmith of Richmond Park (Con) [V]: In 2018, the UK hosted the biggest ever illegal wildlife trade conference, and 65 countries signed up to the London declaration, which committed them to accelerating efforts to stop this vile trade. We are expanding the UK's Illegal Wildlife Trade Challenge Fund, which has committed over £26 million to 85 projects around the world since it was launched. That includes support for the Endangered Wildlife Trust's novel system to detect the pangolins the noble Baroness mentions in shipping containers, by using African giant pouched rats at ports in Tanzania. The UK has supported greater protections for pangolins at the CITES Conference of the Parties, which now means that all international trade in pangolins, or their parts, is prohibited. We will continue to do all we can.

Lord Winston (Lab) [V]: My Lords, I declare an interest as a licence holder who is able to inject animals but not currently able to inject humans with the vaccine. The Covid pandemic has led to a substantial unmet need for more animal research, including on genetically modified mice. We all breathed a sigh of relief with the rapid development of vaccines, which would not have been possible without animal research. This virus affects many different organs, and there is still no substitute for animal models, which we scientists agree must be used ethically and as humanely as possible. Can the Minister reassure the House that he agrees that such research is essential for ensuring animal health and welfare, and the prevention of many human deaths?

Lord Goldsmith of Richmond Park (Con) [V]: Animal experimentation clearly has an enormously important role to play. It needs to be science-led, and there needs

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to be a clear understanding that the results of such research are applicable and useful in the context of human health and medicine. Broadly speaking, the Government's view is that animal experimentation should be minimised to that absolutely necessary in pursuit of human health.

Baroness Parminter (LD) [V]: Does the Home Office plan to make wildlife crime a recordable offence, so that proper statistics can be collected, as what is measured shows what matters?

Lord Goldsmith of Richmond Park (Con) [V]: Recordable offences are set outside Defra, although Defra has been working with, for example, the Raptor Persecution Priority Delivery Group, led by police forces across England and Wales. Our view is that strong penalties are already in place for offences committed against birds of prey and other wildlife, with significant sanctions available to the courts to hand down to those convicted. Most wildlife crimes carry the risk of an unlimited fine and/or a six-month custodial sentence. However, senior government and enforcement officers have identified raptor persecution as a national wildlife crime priority, which means that greater resources will be devoted to clamping down on what we believe has been an increasing crime during the Covid period.

Lord Morris of Aberavon (Lab) [V]: My Lords, in supporting my noble friend Lady Hayman of Ullock's concern to improve enforcement rates, may I say that, as a young man, I occasionally prosecuted gamekeepers and poachers, on behalf of the RSPB, for wildlife crime offences? Will the Attorney-General review the boundaries between private prosecutions and CPS prosecutions to ensure that wrongdoing does not fall between the cracks?

Lord Goldsmith of Richmond Park (Con) [V]: The noble Lord makes an important point and I will convey it to the Attorney-General, on whose behalf I am afraid I am not able to speak. There are now over 500 wildlife crime officers, covering most police forces in England and Wales, and they are specially trained to conduct and support investigations into wildlife crimes. Defra has been supporting work led by the National Police Chiefs' Council and the Home Office to explore widening the range of notifiable wildlife offences in respect of this question and the previous one. The benefit of doing so is that there is a national standard for the recording and counting of these offences by police forces in England and Wales.

Lord Framlingham (Con) [V]: My Lords, one of the many good things to come out of Brexit is our ability to stop the export of live animals for slaughter. I do not expect this practice to have been stopped already, but I trust that it will be as soon as possible. I would be grateful if the Minister could tell us what progress has been made to date and when we can expect to see a total ban in place.

Lord Goldsmith of Richmond Park (Con) [V]: This was a manifesto commitment and we have taken a key step in delivering it by launching, just a few weeks ago, a consultation on ending live animal exports for slaughtering and fattening, as well as further improvements to animal welfare in transport. That consultation closes on 28 January. The Secretary of State has made clear that we want to end live animal exports for slaughtering and fattening by the end of this year. We are currently considering the best legislative vehicles through which to deliver that.

Baroness Hoey (Non-Afl) [V]: My Lords, I very much welcome the decision to have the consultation on the banning of live exports of animals, but I understand that this will not apply to Northern Ireland. Will the Minister do all that he can, as someone who genuinely cares about animal welfare, to get the protocol changed to allow this much-needed consultation to happen in Northern Ireland as well? Or do the Government think that animals in Northern Ireland do not deserve the same welfare treatment as animals in the rest of the United Kingdom?

Lord Goldsmith of Richmond Park (Con) [V]: The noble Baroness makes an important point. As she says, Northern Ireland will continue to follow EU legislation on animal welfare and transport for as long as the Northern Ireland protocol is in place. But I very much take her point and I will convey it to colleagues in government.

Baroness Bakewell of Hardington Mandeville (LD) [V]: My Lords, during the pandemic, more people are buying puppies, many of which are not bred according to our strict animal welfare standards, but are imported illegally, and separated from their mothers too early. As the price of a puppy has risen exponentially, with well over £3,000 being quoted, people are also finding that their beloved pet dogs are being stolen to order. Can the Minister say what the Government are doing to enforce the law on the sale of puppies and to discourage dog theft?

Lord Goldsmith of Richmond Park (Con) [V]: The Government introduced a ban on the commercial third-party sale of puppies and kittens in England, and ahead of that we launched a big national communications campaign strategy called Petfished, which was designed to help people make more informed choices when sourcing a new pet. These are important steps, taken to disrupt the low-welfare trade that supports unscrupulous puppy farming and to tackle the illegal supply of pets. There are already laws in place in relation to pet theft, and it is the view of the Government that the maximum penalties available are sufficient. However, I know that colleagues in government are looking at what changes could be made to sentencing guidelines to reflect the fact that a puppy being stolen is not the same as an inanimate object being stolen. I hope that progress will be made shortly.

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

Gas Boilers and Heaters: Replacement Programme

Question

12.18 pm

Asked by ***Lord Howell of Guildford***

To ask Her Majesty's Government what is their estimate of the total cost of replacing gas boilers and heaters in all homes in the United Kingdom; when any such replacement programme will commence; and what charges will fall on (1) individual households, (2) property owners, and (3) tenants.

Lord Howell of Guildford (Con) [V]: My Lords, I beg leave to ask the Question standing in my name on the Order Paper. I declare my interests as set out in the register.

The Parliamentary Under-Secretary of State, Department for Business, Energy and Industrial Strategy (Lord Callanan) (Con): We are currently developing different pathways to decarbonise heat, and as such it is too soon to estimate these costs accurately. However, the climate change committee estimates that the investment required to decarbonise the entire economy and meet net zero is less than 1% of GDP until 2050. Ensuring that the costs of transition are allocated fairly is a priority, and we will publish a call for evidence on affordability and fairness by April.

Lord Howell of Guildford (Con) [V]: My Lords, I thank the Minister for that reply. These estimates are interesting but, according to the Government's excellent energy White Paper, there are 23 million existing homes attached to the gas supply grid. While it clearly makes sense to equip newly built homes with hydrogen or heat pumps or other technologies, is not the cost of retrofitting all existing homes—estimated by a government research paper at anything between £2,500 and £8,000, or more, per dwelling—and possibly having to replace large parts of the gas delivery grid as well, clearly going to be absolutely astronomical, whether it falls on consumers or taxpayers? Given the tiny contribution, at best, that this whole project could conceivably make to taking over all global emissions growth, is this really the wisest or most effective use of our national resources in combating worldwide climate change?

Lord Callanan (Con): I understand the point my noble friend is making, but we do of course have a legal commitment and obligation to reach net zero emissions by 2050. Of course, 19% of total UK greenhouse gas emissions come from buildings, so we clearly need to take action in this sector. We also marry that up with an ambitious international agenda. We are hosting COP 26 this year and we will seek to persuade our international partners to follow this agenda as well.

Baroness Blower (Lab) [V]: My Lords, there are certainly home owners who live in flats on estates that were possibly originally built as social housing, with communal gas boilers and integrated estate-wide heating and hot water systems. Individual solutions will not be possible in these circumstances. Will the Minister say whether any thought is being given to such circumstances to quantify the problem and, if so, what support will be available to replace or upgrade such systems?

Lord Callanan (Con): I point the noble Baroness to the social housing decarbonisation fund, which will deliver transformational change by upgrading a significant amount of the social housing stock that is currently below EPC up to that standard.

Lord McCrea of Magherafelt and Cookstown (DUP) [V]: In recognising the Government's desire to reduce greenhouse gas emissions throughout the United Kingdom, one must also recognise the need to ensure that the transition is fair to householders and businesses. Therefore, can the Minister tell the House what detailed study has been done to identify any additional costs there will be to run any new heating system? How can we ensure that those living in poverty will be able to bear that financial burden and keep their families warm?

Lord Callanan (Con): The noble Lord is right that we need to make sure that the change is affordable. We have a number of schemes to help low-income families. We have the ECO scheme and the green homes grant scheme, both of which considerably incentivise low-income families to make these changes.

Lord Cormack (Con) [V]: My Lords, may I press my noble friend on this point, bearing in mind that this will be government-enforced expenditure and will place a significant strain on many household budgets? Following this Question Time, will he discuss with the Chancellor the phasing out of all the means-testing of the winter fuel allowance and its replacement at an appropriate time with a boiler grant, especially to all those in receipt of universal credit?

Lord Callanan (Con): We are committed to keeping the winter fuel payment to ensure that older people have the security and dignity they deserve, but we do have boiler grants, as my noble friend referred to them, through the green homes grant that are specifically designed and targeted at poorer members of society.

Lord Oates (LD) [V]: My Lords, I declare my interests as set out in the register. We need to ensure that green hydrogen is the predominant form of hydrogen used in the gas grid and elsewhere. To that end, what consideration have the Government given to using contracts for difference to drive down costs and encourage innovation in the production of green hydrogen, as we did so successfully for offshore wind during the coalition Government?

Lord Callanan (Con): I understand that the noble Lord is very keen on green hydrogen and I agree with him on these points, but we are committed to consult on the preferred hydrogen business model in quarter 2 of 2021 to finalise a decision next year. Alongside this

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we will bring forward further details in 2021 on the revenue mechanisms that will be available to support these proposed business models.

Baroness Neville-Rolfe (Con) [V]: My Lords, planning for the phasing out of all use of gas boilers is, to my mind, a very bold step, especially when the nature of the possible replacements is unclear. What steps are the Government taking to ensure that the energy and construction industries will have the capacity to cope with this change? For example, I understand that there is currently capacity to install only 30,000 heat pumps a year, whereas the need is estimated to be more than 600,000.

Lord Callanan (Con): My noble friend makes some very good points, but the forthcoming heat and building strategy will set out the direction of travel for decarbonising heat. We are working closely with the industry to create the jobs needed to meet net zero. We recently carried out research. There will be enough skilled heat pump installers to deliver our ambitions. We recently published that supply chain research, which shows that heat pump manufacturers are able to meet a significant ramp up in demand.

Lord Thurlow (CB) [V]: My Lords, some 1.75 million boilers are installed every year. I understand that the cost of the hardware alone, using an average price, is in excess of £3 billion annually. Most manufacturers are based abroad and the profits are being sucked out of the UK economy, principally into euros. We must expect these numbers to increase dramatically as fossil fuels are abandoned. Will the Minister please explain what the Government are doing to recapture more of this huge business by encouraging British technologies and British businesses to reclaim this important and growing sector of our economy?

Lord Callanan (Con): The noble Lord is right. We have a number of incentive schemes. I referred to the ECO scheme and the green homes grant scheme. We want to be one of the world leaders in this field and we are working with manufacturers to advance the technology to bring it down to affordable levels to enable its wide-spread use in the UK.

Lord Grantchester (Lab) [V]: The recent energy White Paper stated that

"we will assess the case for encouraging, or requiring, new gas boilers to be readily convertible to hydrogen".

Having recently experienced on 30 December the seizing up of a system boiler, I would like to know what assessment is needed for the Government to require hydrogen-ready boilers to be quoted alongside the conventional, and for the price premium for hydrogen-ready to be reduced progressively towards a conventional price if the consumer or bill payer is unaware of the requirement for all new boilers to be hydrogen-ready by 2025. Is this in the heat and building strategy that the Government are still preparing to publish?

Lord Callanan (Con): We are supporting the development of prototype hydrogen-ready boilers that are not available at the moment through the Hy4Heat programme, which is due to conclude this year. Subject to its findings we plan to consult later this year to seek views from stakeholders on the role that hydrogen-ready appliances will play in the transition to net zero.

Lord McNally (LD) [V]: My Lords, the Minister referred to ground source heat pumps. How realistic are they as a green energy solution in terms of construction and cost?

Lord Callanan (Con): They are one option. Air source heat pumps are another option and hydrogen a third. Domestic retrofit of community energy systems will also play a role. We will need to use a number of different technologies, but ground source heat pumps are certainly one possible technology.

Lord Best (CB) [V]: My Lords, it is clear that retrofitting all UK homes with low-carbon heating is a long way off. Very many households will depend on heating by electricity, which is at present much more expensive than its fossil fuel alternatives. Will the Minister confirm that the Treasury's net zero review is looking at rebalancing the cost of electricity to make it more affordable, not least for those otherwise facing deep fuel poverty?

Lord Callanan (Con): The Treasury's net zero review, to which the noble Lord referred, is considering how the transition to net zero will be funded. Alongside this we are publishing a call for evidence by April to begin a strategic dialogue between government, consumers and industry on affordability and fairness. We have also expanded government support schemes, which I referred to earlier, to those on low incomes, who are likely to benefit from them or to be at risk of fuel poverty. We will respond to our consultation on fuel poverty in due course.

The Deputy Speaker (The Earl of Kinnoull) (Non-Afl): My Lords, the time allowed for this Question has elapsed and accordingly we moved to the third Oral Question.

Essential Services: Large-scale Technology

Question

12.29 pm

Asked by ***Lord Greaves***

To ask Her Majesty's Government what risk assessment they have undertaken of the reliance of (1) the economy, and (2) society, on the use of large-scale technology for the provision of essential services.

The Minister of State, Cabinet Office (Lord True) (Con): My Lords, the critical national infrastructure includes elements of infrastructure that are critical to the availability, delivery and integrity of essential services necessary for the United Kingdom to function and on which daily life depends. The CNI comprises 13 sectors, each with a lead government department responsible for identifying elements of its sector's infrastructure.

Lord Greaves (LD) [V]: My Lords, that was interesting. Modern technology has created amazing and beneficial things but has also resulted in a huge increase in the size and scale of operations, not least in such areas as power generation and supply, transportation networks and, of course, digital systems through the internet. It has also increased centralisation in top-down networks, where major technology or human failures may have catastrophic consequences. Do the Government agree that there must be a radical redesign of our economy and society in order to build in qualities of resilience, recovery and survival, re-engineering systems on the basis of bottom-up and modular operation at as local a level as possible?

Lord True (Con): My Lords, the noble Lord makes some important points of which the Government are aware. I refer to lead government departments and their responsibilities. They are tasked to undertake a review of all the critical national infrastructure sectors to ensure that understanding of what is critical and of risk is up to date and relevant. The review is ongoing, with each lead government department identifying the assets and systems which are essential.

Lord Holmes of Richmond (Con): My Lords, does my noble friend the Minister agree that there are huge advantages to be gained for system and state, and for local and national government, through the considered, ethical, purposeful deployment of digital and emerging technologies for the provision and transformation of essential and non-essential services?

Lord True (Con): I agree with my noble friend. In a sense, his question balances with opportunity the question of risk, to which attention was rightly drawn in the previous question. Technology brings advantages for the delivery of critical services, as my noble friend said. The rapid development of the job retention scheme, with its online portal by HMRC, is a good example of how technology can bring advantages to all levels in a time of need. However, we are also aware that there are risks associated with reliance on technology.

Lord Stirrup (CB): My Lords, in its first report last May, the National Infrastructure Commission acknowledged that security was a question not just of preventing attacks but of how well we could respond to them. It therefore recommended an architecture that would enable us to anticipate challenges and to resist, absorb and recover from attacks and adapt accordingly. Can the Minister tell the House what progress is being made on implementing that recommendation?

Lord True (Con): My Lords, the NIC made some very important recommendations, as the noble and gallant Lord quite rightly says. It is an independent executive agency of the Treasury. A responsive approach is already in place following the May 2020 report. The Government have up to a year to formally respond to the NIC's recommendations, but I assure the noble and gallant Lord that they will be given the most careful attention.

Baroness Pitkeathley (Lab) [V]: Is the Minister aware that certain forms of technology are useful in care settings? For example, Alexa does not mind how many times someone with dementia asks the same question. Does the Minister think that the development of assisted technology—social robots alongside human care givers, perhaps—should be factored into the Government's planning for the reform of social care?

Lord True (Con): My Lords, the noble Baroness makes a profoundly important point, which I agree with. I assure her that all the lead departments involved will consider her points. We must use the future to the benefit of all ages.

Lord Scriven (LD) [V]: My Lords, police use of facial recognition technology can lead to a lack of transparency and accountability, as well as issues of racial and gender bias, as outlined in a recent court case. Does the Minister agree with the Surveillance Camera Commissioner that the Government need to bring forward new rules specifying exactly how, when and where facial recognition technology should be used?

Lord True (Con): My Lords, the specific question is outwith my area of responsibility, but I will pass the noble Lord's comments on to colleagues in the Government, and I certainly note the important point that he has made.

Lord Mackenzie of Framwellgate (Non-Afl) [V]: My Lords, this is a crucial question. Cyberattacks globally on critical infrastructure appear to be increasing with impunity. What plans have the Government got to deter such attacks, particularly by foreign state actors, and have they assessed at what point such an attack could amount to an act of war?

Lord True (Con): My Lords, at my level in Government I will not comment on the final part of the noble Lord's question. He is right that malign cyber activity, including by states, is an ongoing concern. In the Cabinet Office and across Government we are maintaining our capability to respond to major cyber incidents, and the National Cyber Security Centre and law enforcement cyber specialists are active in supporting critical organisations in the UK, including outside government.

Lord Stevenson of Balmacara (Lab) [V]: My Lords, the Ipsos MORI research on understanding the full cost of cyber breaches, published by DCMS last year, points out that the current lack of accurate data makes it very difficult for SMEs in particular to get insurance for such events. Will the Government consider backing a cyber breach reinsurance scheme, based on the successful Pool Re and Flood Re reinsurance schemes, over this interim period?

Lord True (Con): My Lords, once again this is slightly outside my area of responsibility, but the interests of SMEs are always of great concern to the Government and I will pass the noble Lord's suggestion on to appropriate colleagues.

Baroness Wheatcroft (CB) [V]: My Lords, one of the biggest risks of reliance on large-scale technology is the eradication of so many traditional jobs. Would the Minister consider offering retraining to many of the people currently paid to do nothing on the excellent furlough scheme whose jobs are unlikely to have a long-term future?

Lord True (Con): My Lords, the training challenge and broader apprenticeship challenge is ongoing, immense and growing, and I agree with the importance which the noble Baroness attaches to it. The Government are helping to promote cyber skills among young people to fill the shortages in that capacity.

Lord Clement-Jones (LD) [V]: My Lords, controversial algorithms are increasingly being used by central and local government to make decisions. Does the Minister agree that to build and retain public trust we need strong oversight and governance of public sector use of algorithms? What response are the Government giving to the recommendations in the Centre for Data Ethics and Innovation's recent review of bias in algorithmic decision-making, and what plans for regulation do they have?

Lord True (Con): My Lords, again, that is a very broad question, but the issues that the noble Lord addresses are extremely important and I take the sense in which he has offered it. Human judgment is, in the end, irreplaceable—your Lordships' House could never be replaced by an algorithm.

Lord Foulkes of Cumnock (Lab Co-op) [V]: My Lords, but does the Minister accept that some older people are denied access to vital services because of digital exclusion? Will the Government support means to help increase their access and provide an alternative way of accessing services for those who are unable to access the internet?

Lord True (Con): My Lords, the noble Lord makes a very important point. Looking at the colour of our hair, he and I should declare an interest in this matter. We need to extend understanding and use of technology, and access to it, but equally I urge all organisations, including banks, to remember that for many people a personal service is not only a matter of choice but a matter of necessity.

The Deputy Speaker (The Earl of Kinnoull) (Non-Afl): My Lords, the time allowed for this Question has now elapsed and we therefore move to the fourth Oral Question.

Cannabis Oil

Question

12.40 pm

Asked by ***Baroness Walmsley***

To ask Her Majesty's Government what steps they are taking to ensure that cannabis oil continues to be legally available to patients when prescribed by their physician.

The Parliamentary Under-Secretary of State, Department of Health and Social Care (Lord Bethell) (Con): My Lords, we are on the case. I completely recognise the problems faced by Alfie Dingley and all the individuals reliant on the previous arrangements with the Dutch Government for the supply of Bedrocan oils. The department is working urgently with Dutch Minister Tamara van Ark to find a solution that will enable these patients adequately to access the medications they need, and we are committed to setting up clinical trials to inform future NHS commissioning of cannabis-related medicines.

Baroness Walmsley (LD) [V]: My Lords, I thank the Minister for that very encouraging response. He will know that time is of the essence because these medicines prevent children having severe fits, some of which are life-threatening. Can he go back to his department and educate some of his officials? Unfortunately, a lot of the families are very upset at being told that they can safely be switched to an alternative formulation. That is both ignorant and dangerous. All the expert clinicians who know about these issues say that that cannot be done safely. Even if it could, eventually putting these children back on to the original formulation sometimes does not work. Will he make sure that his officials listen to the clinicians who are expert in prescribing and in following the progress of people on these formulations?

Lord Bethell (Con): My Lords, I am grateful for the noble Baroness's kind words, and I will indeed take that patient feedback back to the department. I reassure her that this is an area where patients have undoubtedly led the way, and clinicians have to catch up. In doing so, there will need to be a meeting of minds and regulation in areas that are open to patient interpretation. In that period, there will undoubtedly need to be compromises on all sides.

Baroness Warwick of Undercliffe (Lab) [V]: My Lords, the law changed over two years ago. The then Home Secretary said:

> "We have now delivered on our promises … we will work with the NHS to help support specialists in making the right prescribing decisions."

But they have not; it has been a hollow promise for terminal brain cancer sufferers such as my nephew. NHS doctors will not prescribe medical cannabis, and the BMA advises medics not to prescribe it, yet I understand that the UK is the largest producer of medical cannabis in the world. Just how many prescriptions have been issued for unlicensed cannabis medicines, other than those subject to randomised control trials, in the last 12 months?

Lord Bethell (Con): My Lords, the noble Baroness is being a little unfair; Health Education England published a medicinal cannabis education package on 8 August 2019. But we cannot force clinicians to make prescriptions. That is not how the health service works. We need to work on clinical trials to put in place the correct authorisations and to give marketing authorisations for these important and promising drugs. That will

require collaboration between government, the regulator and industry, and I call on industry to step up to that challenge.

Baroness Barker (LD): My Lords, some people in England and Wales are reliant on hormone therapies produced in the EU 27. Who precisely in the NHS is responsible for ensuring continuity of supply of those therapies to patients?

Lord Bethell (Con): My Lords, procurement decisions in the NHS are done by the NHS. I do not think that a specific or unique group is focused precisely on hormone therapies, but I would be glad to go back to the department and write to the noble Baroness to confirm that.

Lord Mancroft (Con) [V]: My Lords, I draw your Lordships' attention to my interests as set out in the register. If we can vaccinate 1.5 million people in a few weeks with a drug that did not even exist a couple of months ago, how come we cannot prescribe properly a drug that has been legal to prescribe for over two years? Cannabis contains over 120 different cannabinoids and eight terpenes, and the way in which these are configured makes a world of difference to their effectiveness. What training is being given to ensure that the right combination of cannabis oil required to treat different medical conditions is correctly prescribed? I think it is time that the Government stepped up to the plate on the training.

Lord Bethell (Con): My Lords, I would turn around my noble friend's proposition and ask this question. If many vaccine manufacturers can turn around clinical trials in eight months for an extremely complicated vaccine, how come the cannabis-producing companies cannot turn around clinical trials over years?

Lord Field of Birkenhead (CB): I thank the Minister for his reply. I declare that I am a cannabis user to counter pain, and no doubt later today we will be able to come back to that issue. I hope that his officials are watching to witness the support there is in this place for the role that he is trying to secure so that young sufferers who shake their brains to pieces might get relief today rather than tomorrow, when it is too late.

Lord Bethell (Con): I thank the noble Lord for sharing that personal testimony, which is extremely touching and relevant. I share with him that there is a large amount of ministerial support for the principle of this exciting and interesting area. If there is any frustration on my behalf, it is only that somehow the industry has not matured to the point that it can sponsor the kinds of clinical trials that can take these important medicines through the necessary authorisation process that can put them on the NICE list so that they are available for more patients.

Baroness Thornton (Lab): It is not surprising that people are astonished that important cannabis products, which can transform the lives of those suffering from debilitating, painful conditions, are approved yet still not available—and in some cases supply has been disrupted as a by-product of Brexit. Would the Minister care to speculate as to why this has not happened? It is not just that the companies have not stepped up—why have they not done so? Would the political will that has been brought to bear on various other issues faced by this Government, such as Brexit, not be usefully brought to bear on this one?

Lord Bethell (Con): The noble Baroness puts a very reasonable challenge to the life sciences arrangements in the UK. We are blessed with major pharmaceutical companies, and a lively and exciting biotech industry, all of which are well plugged into the regulatory authorisation process. This is a novel, exciting, patient-led and innovative area. For those reasons, it has not had the financial backing of either business or the financial institutions to put in place the very simple, straightforward requirements of clinical trials, which are there for patient safety in the first place, not for government box-ticking. We are working extremely hard to try to resolve this Catch-22 situation and I hope very much indeed that we will be able to announce news on that shortly.

Lord Addington (LD): My Lords, it is nice to hear that the Government are taking this problem seriously. If these drugs are effective, would it not be a good idea to encourage the demand side of this equation, where doctors prescribe them, by pointing out what the drugs allow a child with epilepsy, for example, to do—that is, lead a normal life, get educated, get qualified and be able to have a job—and the cost to the state if they do not?

Lord Bethell (Con): The noble Lord alludes to an important, although frustrating, point. If I may gently push back, the truth is that there is a large amount of very persuasive anecdotal evidence, some of which we have heard today. It is completely compelling—it is just not scientific. Patient safety relies on extremely rigorous clinical trial regimes; that is why we have safe medicines in the UK. It is simply not possible to persuade front-line clinicians to make prescriptions on the basis of anecdote rather than clinical study.

Baroness Stuart of Edgbaston (Non-Afl) [V]: My Lords, I am delighted that the Minister is on the case and that we can make sure that this issue is resolved for this set of parents. On a wider note, however, would the Minister consider revisiting the NICE guidelines, last published in November 2019, which had a list of recommended research, to ensure that we potentially widen the base of research and bring more speed into the process?

Lord Bethell (Con): The noble Baroness is right that research is the key. I reassure her that we are looking at ways to try to bring research forward. The issue is not with the NICE guidelines themselves; it is with getting the scientifically backed data to be able to justify the authorisations from the MHRA. We are working extremely closely with the NIHR. We are looking at the NHS, which, as the noble Baroness likely knows,

[LORD BETHELL]
does have manufacturing capability within itself for these kinds of drugs. As some noble Lords here will know, we are engaged in thoughts about how the NHS manufacturing capability can be used to mobilise clinical trials in this important area.

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.

Arrangement of Business

Announcement

1 pm

The Deputy Speaker (Baroness Garden of Frognal) (LD): My Lords, the Hybrid Sitting of the House will now resume. I ask Members to respect social distancing.

Covid-19: Vaccine

Private Notice Question

1.01 pm

Asked by ***Baroness Deech***

To ask Her Majesty's Government what evidence they have that delaying a second dose of the Pfizer-BioNTech Covid-19 vaccine will not (1) diminish its effectiveness, or (2) cause further mutations in the virus.

The Parliamentary Under-Secretary of State, Department of Health and Social Care (Lord Bethell) (Con): My Lords, the views of the MHRA and the JCVI, based on the data submitted from extensive clinical trials, is very clear: a single dose gives very high protection from the virus 10 days after the first dose. A second vaccine dose is important to sustain that protection and extend its duration. Of course, it makes sense to vaccinate as many people as possible as quickly as possible to protect their lives and safeguard the NHS, which is why we take the approach that we have.

Baroness Deech (CB) [V]: My Lords, today we are discussing the safety of medicines. Only moments ago, the Minister was emphasising just how important that is. Yet in delaying a second dose, the whole country is being treated as an experiment. Pfizer has said that the trial of the vaccine was on participants who received a second dose within three to four weeks. There is no data, it said, to demonstrate that protection after the first dose is sustained after 21 days. The WHO also says that there is no scientific evidence supporting the delay beyond six weeks. No other country is doing it. The UK is taking a gamble that risks fostering vaccine-resistant forms of the virus. Will the Minister mitigate the risks and ensure that a second dose is given at 21 days, until there is independent scientific advice and evidence for the delay?

Lord Bethell (Con): My Lords, I remind the noble Baroness that Pfizer is not a regulator, nor is the WHO. Other countries are working on vaccines, but they are behind the UK in terms of authorisation and rollout. I reassure her that there is data, which is published on the internet. I tweeted a copy of it late last night, and I invite her to have a good, close look at it because it is absolutely categoric: one dose is enough.

Lord Campbell-Savours (Lab) [V]: There is a heated debate going on in the United States, as reported on CNN, over the incidence in use and registration of both the first and necessary second vaccinations with particular concern over the second, without which the first is less effective, despite what the Minister has just said. What plans do the Government have in the United Kingdom to ensure compliance with the necessary take-up of the second vaccination and the registration of both by the authorities?

Lord Bethell (Con): The noble Lord is entirely right: the second dose is important. However, it is important not for efficacy but for durability. We have put in substantial data provisions to record every single dose into every single arm, and to put a follow-up dose into exactly those arms. We are using the NIMS system and every single vaccination is put into the GP record. They will be tracked down extremely diligently for exactly the reasons that the noble Lord describes.

Baroness Brinton (LD) [V]: My Lords, a number of scientists have expressed concerns about delaying the second dose of the Pfizer/BioNTech Covid vaccine. On the excellent Radio 4 programme "How to Vaccinate the World", Professor Sir David Spiegelhalter said that, as the RNA technology used is new, there is less data to give confidence on spacing. But he suggested that, given a number of people have received their first dose, now is the perfect time to do a small randomised research trial on comparing those receiving their second dose at 21 days and others receiving it at 12 weeks, which would then perhaps give more confidence. Is that happening?

Lord Bethell (Con): Who can hold a torch to Professor Spiegelhalter and his analysis of the data? Although I did not hear him, I completely welcome his comments. I reassure the noble Baroness that enormous efforts are being put into the pharmacovigilance around this vaccine. Some of this is of a clinical and scientific nature, and it takes a while to read out. We have therefore put in parallel systems to get an early read-out on exactly the kinds of questions that she has asked.

Viscount Eccles (Con): My Lords, as an interest, I can report that Lady Eccles and I have both had two Pfizer jabs, three weeks apart. At the planned rate of 2 million vaccinations a week, there will be the equivalent of 1 million people being fully vaccinated, whatever the gap. There will also be a continuing critical path through this rollout, which is complex. It may start by being vaccines, which are the limiting factor, but it could become otherwise. Can we be assured by my noble friend that the NHS is fully prepared to identify

and deal with the critical path? Can we also be assured that we will get clear and full information on progress, and about the actions being taken to maintain that progress?

Lord Bethell (Con): I congratulate my noble friend and Lady Eccles on their double vaccinations. It is one of the most heartening experiences of a pretty dreadful year to witness the rollout of this vaccination and the joy and reassurance it brings to those who have been vaccinated. I reassure my noble friend that the NHS is absolutely putting the resources in place not only to roll out the single and second vaccinations to everyone over 18 who will step up for those but also for the pharmacovigilance to ensure that any adverse effects are recorded through the Yellow Card scheme and that those records are analysed and acted upon so that any changes or tweaks, as sometimes happen, are enacted by the NHS to get the best possible outcome for as many people as possible.

Baroness Hayman (CB) [V]: My Lords, may I ask the Minister another question about evidence? When do the Government expect to have clear advice on the possible transmission risk from those who have been vaccinated? Everyone I know who has received the vaccine—they have been delighted to do so and impressed by the efficiency of the NHS—is now talking about meeting their Pfizered friends, seeing grandchildren and returning to volunteering or to your Lordships' House. Does the Minister acknowledge that there will need to be cogent and clearly communicated advice for those who have been vaccinated, many of whom have been in virtual isolation for nearly a year?

Lord Bethell (Con): The noble Baroness delivers tough news to her friends and to the Chamber, and I completely agree with her analysis. The frustrating truth is that, while the efficacy of the vaccine has been tested on hundreds of thousands in clinical trials, and we can lean on that data extremely well, the transmissibility of those who are immune is not yet clear. We have put in place trials and testing regimes to understand and get to the bottom of this point. But she is entirely right: it is possible, although not proven at the moment, that those who are themselves immune are not sterile but vectors of infection. Were they, for instance, to return to this Chamber, they would potentially infect those of us such as my noble friend Lord Parkinson, who is extremely young and does not qualify for the vaccine any time soon, and who could catch the virus off an octogenarian noble Lord in an instant.

Baroness Thornton (Lab): The noble Baroness, Lady Hayman, raises the most important issue, which is communication and the way that the Government may allay anxiety. Something which has been put to me is that we know the risks to human health run by the creation of antibiotic resistance and the creation of mutant and resistant bacteria as a result of misuse, including inadequate doses. Can the noble Lord assure the House that immunologists are being consulted? What is their view of this risk? Anxieties are being expressed in many different ways, so there has to be better communication about this issue.

Lord Bethell (Con): The noble Baroness is right that communication is key. We seek to explain the scientific basis of this vaccine, and a huge amount of effort has gone into what I call "O-level biology communications." This is one of the reasons why acceptance rates appear to be—touch wood—as high as they are at nearly 90%. Had someone told me that number a few months ago, I would have happily settled for it. She is right, the escapology of this virus is just the same as it is under AMR. From very early analysis it would appear—and this is extremely conditional—that the recent variant is not escaping the vaccine or any of the therapeutics we have put in place. However, it is more performance enhancing. That is good news for the vaccine and bad news for the prospect of having a disease present in society and the world for some time to come.

Lord Roberts of Llandudno (LD) [V]: My Lords, this virus is unchartered hostile territory and we can but rely on the best scientific advice. Some will say that delaying the second jab might even be advantageous and others will disagree. By delaying, debating and disagreeing we are going to put many thousands of lives at risk, lives which could have been saved by having that first jab. I am not qualified to say which is the best; I wish I was. I can only in gratitude accept the guidance of experts and that is what I will do. In doing so, I think that hundreds or thousands of extra lives will be saved by that first jab.

Lord Bethell (Con): The noble Lord alludes to a complicated dilemma that we all feel. I welcome challenge and those who query and question the basis of our policy decisions and our science. He is right: too much false information and fake news can damage trust. We have gone about the vaccine process with an approach that is as open and transparent as it can possibly be. We have sought to engage in dialogue and answer questions where there have been any. That approach has proved to be effective and it is the one we continue with.

Baroness Browning (Con) [V]: My husband, who is 84 years old, received his Pfizer vaccine before Christmas and his second one last week was cancelled. Is there any guarantee that, when the second jab comes, it will be the Pfizer vaccine? As I understand, there has been no research on mixing and matching these vaccines. Is there any way that the level of immunity can be tested at that three-month point?

Lord Bethell (Con): The CMO has made it clear that he leans heavily towards having consistent vaccines, but it is not a requirement. Some of the immune response comes from antibodies which can be tested, but some of it is from T-cells, which are very difficult to test for. It is not possible to categorically say whether someone is immune. However, we have looked at ways to measure and understand more about the body's immune response to develop our understanding in this area.

Baroness Masham of Ilton (CB) [V]: My Lords, what is the chance that, if the second Pfizer vaccine dose is delayed, the virus could become resistant to the

[Baroness Masham of Ilton]
vaccine? For what reason do Pfizer and the World Health Organization recommend three weeks between the vaccines?

Lord Bethell (Con): The noble Baroness is right; this virus could mutate and start escaping the vaccine. That is a very real threat. The good news is that we know so much about it now, have digitally mapped it and have grown it so many times in the laboratory, that making new vaccines would be a relatively straightforward process. It would not necessarily require the months of clinical trials that the first one did. However, be under no illusion, were this to happen it would set our vaccine deployment back considerably.

Baroness Pidding (Con) [V]: My Lords, I appreciate the necessity of getting as many people vaccinated as possible and the need therefore to be agile and flexible in making policy decisions. However, would the Minister agree with me and other Lords that it is also critical we win the battle of communications? We need to ensure that we take the public with us, with a clear understanding and a clarity of message.

Lord Bethell (Con): The central proposition we are discussing is that it is better to double the number of people getting their first jab, even if there is a marginal decrease in the efficacy of the vaccine for a few people. That message has got through to the public and I think it enjoys tremendous public support. I acknowledge the concern that some will naturally feel about what appears to be a diminution in provision, but I am here to reassure and provide consistent scientific advice that is not the case.

Lord Vaux of Harrowden (CB) [V]: My Lords, two logistical questions are raised by delaying second doses. First, given AstraZeneca's statement yesterday about variability of manufacture, together with the increasing global demand going forward, how will the Government guarantee we have enough vaccines of the right type for all second doses at 12 weeks? Secondly, am I right that from the end of March the rate of new vaccinations will fall sharply, because we will then need 2 million doses per week just to cover the second doses?

Lord Bethell (Con): I think the noble Lord has read too much into the AstraZeneca statement. Negotiations with AstraZeneca and provisions in manufacturing capacity are extremely well advanced. All the projections in the vaccine plan published yesterday have been bottomed out and secured with manufacturers and deployment. The Secretary of State was very clear about the objectives of 13.6 million by the end of February and the whole country by the autumn. Those are not vague reassurances; those are bottomed out and have business plans behind them.

The Deputy Speaker (Baroness Garden of Frognal) (LD): My Lords, the time allowed for this Private Notice Question has elapsed. I apologise to the noble Baronesses, Lady Uddin and Lady Gardner of Parkes, that there was not time to take their questions.

Economic Update

Statement

The following Statement was made in the House of Commons on Monday 11 January.

"Before I begin, I am sure the whole House will join me in sending our very best wishes to my right honourable friend the Member for Old Bexley and Sidcup (James Brokenshire). I have been fortunate in having worked closely with him, and he is one of the nicest and most decent people in politics—a fantastic Minister and a tireless advocate for his constituents. We all look forward to his speedy recovery and to seeing him back in this place as soon as possible.

Last week, the Prime Minister set out the actions that we must take to control the spread of coronavirus. With your permission, Mr Speaker, today I will update the House on the economic situation we currently face, the action we are taking to support the British people and businesses through the crisis, and the factors influencing our outlook.

As the House knows well, coronavirus has already caused significant harm to our economy. The scale of the impact bears repeating. GDP fell by 18.8% in the second quarter of 2020. While the economy grew as the country opened up over the summer, it remained 6.7% smaller than it was before the crisis. The Office for Budget Responsibility's November forecast showed GDP falling again in the final quarter of last year and it forecast the largest fall in annual output for over 300 years. Even with the significant economic support we have provided, more than 800,000 people have lost their jobs since February. While the new national restrictions are necessary to control the spread of the virus, they will have a further significant economic impact. We should expect the economy to get worse before it gets better.

In response, the Government have put in place a comprehensive economic plan. We have provided a fiscal stimulus of over £280 billion to fund our plan for jobs, to support public services like the NHS, and to provide financial support for millions of people and businesses. Some 1.2 million employers have furloughed almost 10 million employees. Almost 3 million people have benefited from our self-employment grants, taking the total support for the self-employed to nearly £20 billion. Over 1.4 million small and medium-sized companies have received government-backed loans worth over £68 billion. Tens of billions of pounds of tax cuts, tax deferrals and cash grants have been delivered to businesses, and the United Kingdom Government have guaranteed at least £16.8 billion of additional funding for the devolved Administrations in Scotland, Wales and Northern Ireland.

In response to the new national lockdown, we are extending and increasing our financial support. We are providing a bridge for people and businesses until the economy reopens, to give them the chance to rebuild productive capacity. To do that, we have extended the furlough scheme to April, we are supporting self-employed people with a fourth income grant, and we have announced, alongside the introduction of new restrictions, an extra £4.6 billion to protect UK jobs and businesses. All business premises in England that are legally required to close, including in retail, hospitality

and leisure, can now claim one-off grants of up to £9,000 for each of their business premises, benefiting more than 600,000 businesses and coming on top of the existing grants worth up to £3,000 paid each month. We have also made discretionary funds of £500 million available for local authorities in England to support local businesses in those areas, on top of the £1.1 billion of discretionary funds that we have already provided to local councils.

Sadly, we have not been and will not be able to save every job and every business, but I am confident that our economic plan is supporting the finances of millions of people and businesses. Across almost all areas of economic policy, we are providing comparable or greater support than all our international peers. As the Office for Budget Responsibility, the Bank of England and the International Monetary Fund have all recognised, our economic response is making a difference by saving jobs, keeping businesses afloat and supporting people's incomes.

Looking forward, there are signs of hope. First, with the vaccine, we can start to see a path out of coronavirus. Vaccine rollout is our most important economic lever and we have made available over £6 billion. We have now administered over 2.4 million vaccine doses across the United Kingdom, and by 15 February we aim to have offered a first vaccine dose to everyone in the top four priority groups identified by the Joint Committee on Vaccination and Immunisation.

Also, the data shows that there are potential sources of underlying resilience in our economy. In aggregate, we have seen the household savings ratio reach record levels and, taken as a whole, corporate sector cash buffers have improved. And of course, we have now agreed a new trading partnership with the European Union. We have removed that uncertainty from businesses and can now start to do things differently and better—not least in financial services, where in November I outlined for the House our plan to reinforce the UK's position as a globally pre-eminent financial centre.

While the vaccine provides hope, the economy is going to get worse before it gets better. Many people are losing their jobs, businesses are struggling, and our public finances have been badly damaged and will need repair. The road ahead will be tough. Now it is time for responsible management of our economy, taking the difficult but right long-term decisions for our country, but I am confident that, with this comprehensive support that the Government are providing and, above all, the determination, enterprise and resilience of the British people, we will get through this. I commend this Statement to the House."

1.17 pm

Lord Tunnicliffe (Lab) [V]: My Lords, as ever I am grateful to the Minister for putting this Statement on the record and leading our scrutiny of it. The picture painted by the Chancellor yesterday was a bleak one. Given that his personal brand centres on optimism, it is clear why he has resisted appearing before the Commons until now. Before turning to yesterday's Statement, I gently say to the Minister that announcing £4.6 billion of expenditure via a Written Ministerial Statement last week was wrong. I hope he will assure us that both Houses will receive verbal updates in future.

As outlined in the Statement, economic performance in 2020 was understandably poor by conventional standards. The Minister will doubtless disagree with me, but this was arguably exacerbated by the stop-start nature of the Government's response to the pandemic. The outlook for the economy this year and beyond is equally worrying. Even with nifty accountancy tricks, the projections fall far short of where we would like to be. I have commented previously about the speed at which the OBR predicts annual economic growth will flatten out at an unremarkable 2%. I have regrettably seen and heard nothing from the Government which resembles a plan for addressing that concern. We recognise, as we have at all stages of the Covid-19 crisis, the colossal scale of state intervention over recent months. It has been unprecedented, but there is no doubt that challenging times call for such measures.

The Minister will know that we are fast approaching a calendar year since the first national lockdown and the launch of various economic measures that accompanied it. Despite the passage of so much time, current support still falls far short of the Chancellor's pledge to do "whatever it takes" to help the nation through these tough times. The Government say that not every job can be saved, but more could have been rescued had Mr Sunak provided greater certainty on employment support last year rather than trying to extricate himself from it at the earliest opportunity—in the face of all available evidence. As sure as night follows day, the U-turn came, but the harm had already been done. It is ironic that he now appears to champion the furlough scheme as one of his greatest achievements.

We needed swifter intervention in the creative industries, to support hospitality firms and supply chains, and to support the aviation sector. Despite their worth to our economy, many unanswered questions remain about the future of these sectors. Ministers have shamefully refused to address well-documented shortcomings of the Self-employment Income Support Scheme, where arbitrary criteria have left millions relying on universal credit, which is already insufficiently generous and at risk of a significant cut from April. We would have accepted a declaration of intent in the event of full details not being ready; as it happens, we did not get even an acknowledgement of the problem.

The Chancellor could and should have used yesterday's Statement to outline his plans for addressing these issues and many more, including backing local authorities rather than forcing them to raise council tax. Compliance with guidance on self-isolation is believed to be heavily influenced by an individual's financial circumstances. The Chancellor knows this yet failed to announce new incentives to help people do the right thing. His Statement was also a missed opportunity to provide much-needed additional help for the homeless, who have, tragically and literally, been left out in the cold. Can the Minister shed any light on why these issues were not directly addressed in the Statement? Can we expect them to be addressed soon, or will the Government continue to hide behind flimsy and unsubstantiated claims?

We are trying our best to support the Government as they tackle this pandemic, and will continue to do so. However, to rebuild public confidence in their response, we need greater honesty, accountability and consistency. The arrival of multiple vaccines against

[Lord Tunnicliffe]
this coronavirus is crucial in our fight to overcome it, but we are still getting different messages and timeframes depending on which member of the Cabinet we hear from. Whether it is in respect of the number of Covid-19 infections and deaths, the state of our economy, the struggle to end inequality or even Brexit disruption to supply chains at border crossings, Ministers warn almost daily, apparently without contrition, that things are likely to get worse before they get better.

We understand that the new strain required changes to plans over Christmas, but, as with the furlough U-turn, clarification came much too late. Despite that experience, the Government have set themselves the target of schools returning after the February half-term and life beginning to look more normal by Easter. Does the Minister stand by these dates? If it transpires that they will be missed and children will remain at home, will the Government look for additional help for teachers and a legal right for parents to request paid, flexible furlough? Can the Chancellor announce future financial support at the earliest opportunity, to give businesses and workers maximum certainty?

Baroness Kramer (LD) [V]: The Chancellor has once again responded to a long-term economic crisis with only very short-term measures. The evidence from the Resolution Foundation of sharply growing inequalities is scary, frankly, as low-income families have to spend more to survive the pandemic. Will the Government at least make permanent the £20 uplift in universal credit?

Economic recovery cannot take hold before the summer even with a successful vaccine rollout, so will the Government now extend furlough, SEISS, the loan and various other support schemes at least to July, if not beyond?

Why have the Government continued to exclude 3 million of the self-employed from help, especially now that the Federation of Small Businesses has devised a scheme that avoids the risk of fraud? The FSB has also pointed to the recapitalisation crunch that could destroy businesses in 2021. Where is the long-term economic plan for recovery that businesses need to enable them to hang in, protect jobs, invest and grow again?

The Minister of State, Cabinet Office and the Treasury (Lord Agnew of Oulton) (Con) [V]: My Lords, I am grateful to the noble Lord, Lord Tunnicliffe, for his comments. I shall to try to address some of his points.

It is clear that the UK, along with the rest of the world, continues to face economic disruption in the wake of the Covid pandemic. No major economy has avoided a dramatic fall in its GDP in the past year. In the face of the significant and far-reaching impact of Covid, the Government's priority has been to protect lives and livelihoods with a flexible and adaptable response. This response is one of the largest and most comprehensive in the world, totalling more than £280 billion since March. The IMF judges the UK's initial response as being aggressive, effective and an excellent example of well-co-ordinated action.

While we should expect the economy to get worse before it gets better, as my right honourable friend the Chancellor said yesterday, there are reasons to be cautiously optimistic for the future. The peak of the unemployment rate is expected to be significantly lower than that estimated earlier in the crisis. The OBR has revised down its central scenario from 12% in July's estimate to 7.5% in November's estimate. The household savings ratio has reached its highest level since records began in 1963. The corporate sector cash buffers have improved, with large businesses making large net repayments every month since May. The furlough scheme has seen some 1.2 million employers and almost 10 million employees supported and has been extended until April to provide certainty during these difficult times. We have provided significant support to the creative industries through the £1.5 billion Culture Recovery Fund and to the hospitality industry, which I recognise has been severely impacted by the restrictions. It has also been supported by cash grants, loans, VAT reductions and deferrals, and business rate holidays.

The support for the self-employed has been unprecedented and among the most generous of schemes in the world. It has so far supported almost 3 million people at a cost of nearly £20 billion. As the Chancellor has said, sadly we are not able to save every job and business and, in recognition of this, have boosted the welfare system by £7.4 billion in 2021.

I thank the noble Lord for mentioning the vaccine, which represents a significant sign of hope and a path out of the coronavirus. Vaccine rollout is our most important economic lever and we have made available more than £6 billion to facilitate that. We have now administered more than 2.4 million vaccine doses across the UK. By 15 February, we aim to have offered a first vaccine dose to everyone in the top four priority groups identified by the Joint Committee on Vaccination and Immunisation.

The road ahead remains tough, with significant uncertainties. The Chancellor and this Government will continue to work to support individuals, businesses and public services during this time. As the Chancellor said yesterday, he will provide an update on the next stage of our economic response to coronavirus and the economic outlook for the rest of the country in the Budget on 3 March.

On retaining the uplift in universal credit, referred to by the noble Baroness, Lady Kramer, as with all responses so far in the crisis, we have tried to adapt to changing circumstances and this matter will be kept under continual review. In the same vein, we have extended furlough until April, it already having been extended from an earlier time, and we will continue to be alert to the state of the economy.

On the noble Baroness's point about the self-employed and the Federation of Small Businesses, my right honourable friend the Chancellor said yesterday that he was considering the ideas put forward by the FSB.

The Deputy Speaker (Baroness Garden of Frognal) (LD): My Lords, we now come to the 30 minutes allocated for Back-Bench questions. I ask that questions and answers be brief so that I can call the maximum number of speakers.

1.30 pm

Lord Balfe (Con): My Lords, I will quote from the Statement, where the Chancellor said:

"Across almost all areas of economic policy, we are providing comparable or greater support than all our international peers."—[*Official Report*, Commons, 11/1/21; col. 23.]

We are supporting with borrowed money and using the inheritance of the country. When the Government cut back, as they inevitably will have to, they will be opposed and told that they should spend more. I will ask two questions. Do the Government have any perspective on getting back to a balanced budget? And have the Government factored in the possible impact of increases in interest rates on the amount they will have to pay back on all the money that has been borrowed?

Lord Agnew of Oulton (Con) [V]: The noble Lord asks very important questions. I am not in a position to give a date by which we will attempt to rebalance the budget, but I assure the noble Lord it is a very high priority. Indeed, on his second question, we are aware that we are able to borrow large sums of money at the moment because of the very low interest rates that will not necessarily remain, which re-emphasises the need to bring the budget back into balance as soon as possible.

Lord O'Neill of Gatley (CB) [V]: My Lords, I would like to, once more—I have done so before—compliment the Chancellor and the Treasury on their general agility in their policy response to this unpredictable, ongoing and, at times, devastating twist in the pandemic. I have two very brief questions. First, in view of the highly appropriate importance being attached to the speed of the vaccination programme, and the high level of personal savings that has built up, as the Chancellor acknowledged yesterday, has the Treasury undertaken—if it has not, perhaps it might consider doing so—exploring research that directly links the speed of vaccine rollout to business and consumer confidence in an effort to encourage more people to take the vaccine and to build confidence across our society? Secondly—this links to what has already been raised—are we to believe that, once more due to the severe complications brought about by the new variant, further specific policies on the crucial levelling-up agenda, which the Prime Minister and his Cabinet frequently refer to, are likely to be delayed again, and that the planned March Budget is likely to be yet another Covid-19 support-based event?

Lord Agnew of Oulton (Con) [V]: The first question, on the link between vaccination rate and economic confidence, is absolutely fundamental. I am not aware of specific research being done on that. If there is any, I will make the noble Lord aware of it. From my own interaction with businesses, there seems to be a strong sense that the two are intertwined, which is why we are putting so much emphasis on it.

I reassure my noble friend that the commitment to levelling up remains as strong as ever. We will be making a Statement in the next few days on our progress in moving civil servants out of London and into some of the areas that the noble Lord refers to. My right honourable friend the Chief Secretary has a large fund for levelling up, for which regions can bid, and that is moving forward as well.

Viscount Chandos (Lab) [V]: My Lords, the Economic Affairs Committee, of which I am a member, urged the Government in December to make the £20-a-week increase in basic universal credit permanent, as the noble Baroness, Lady Kramer, has done today. We may not be known for our footballing prowess, but the committee, chaired by the Minister's noble friend Lord Forsyth, is hardly partisan. The Minister said that the Government were responsive to changing economic conditions, and these have only deteriorated since the committee's report. Why does the Minister not commit now to this, thereby mitigating the deep anxiety of an inevitably increasing number of recipients, rather than prevaricate until only days before the scheduled expiry of the temporary increase?

Lord Agnew of Oulton (Con) [V]: As I said in my earlier comments to the noble Baroness, Lady Kramer, I am not able to give the commitment the noble Lord asks for. The Chancellor will give an economic update in his Budget on 3 March, and I am sure that this matter will be addressed then.

Lord Fox (LD) [V]: My Lords, in the self-congratulatory response of the noble Lord, Lord Agnew, he favourably mentioned the household savings ratio. As my noble friend said, this pandemic will hit poorest families hardest; they are already having their incomes squeezed, and they have no savings at all to see them through this. It is clear also that the most deprived in the UK are the least likely to self-isolate; given the current level of support, they simply cannot afford to. The poorest people in this country cannot afford to wait for a March Budget and, despite the Minister's smug response, this Statement offers them nothing. So can the Minister explain why the Government are blind to the fact that adequately helping the poorest people in this country is not only right but vital in the national fight against Covid?

Lord Agnew of Oulton (Con) [V]: I would remind the noble Lord of the large number of interventions we have made which will substantially support the most vulnerable in society: support to renters to reduce the ability to force evictions; the mortgage holiday, which has been granted to 2.7 million people since last March; the support in the many individual programmes we have announced. All these are applicable to some of the poorest in our society. We are very aware of their vulnerability. I would gently remonstrate with the noble Lord that it was not a statement of self-congratulation when I was answering the noble Lord, Lord Tunnicliffe; it was merely a statement of what we have done over the last 10 months.

The Lord Bishop of Birmingham [V]: I am grateful for the much-appreciated provisions made by the Chancellor so far in this extreme crisis and for his honesty in outlining the significant harm already caused to the economy by the pandemic. Will the Minister reassure the House that, following these emergency measures, many of which have been outlined just now, there are plans and policies already being formed for a recovery? Would he indicate some of the economic and social principles that the Government will be applying in leading the recovery? In addition to the question from the noble Lord, Lord Balfe, will the inevitable need to rebalance the public finances not unfairly burden the poorest?

[The Lord Bishop of Birmingham]

I have another question. Will the Minister draw on the wisdom of the Institute for Fiscal Studies Deaton review, which is seeking to understand the UK's complex mix of unacceptable inequalities and how to alleviate them? It takes into account the hollowed-out jobs market and the need for more crucial investment in education, skills and vocational training, as our willing, talented and diverse population competes with dignity and enterprise in the global market.

Lord Agnew of Oulton (Con) [V]: The right reverend Prelate asks important questions. I can assure him that very active thinking is going on about how to come out of this awful event as quickly as possible. I will mention one or two examples. The Kickstart scheme is designed to support hundreds of thousands of newly and fully subsidised jobs for young people. By the end of December, 50,000 Kickstart jobs had already been created. Additionally, £2,000 is being paid for each new apprentice taken on. I mentioned in answer to an earlier question our levelling-up commitment and the funds behind that. Those again will go to the regions where some of the most vulnerable people in this country live.

Lord McLoughlin (Con) [V]: I much appreciate many of the financial decisions the Government have taken—at very short notice, in some cases. However, will the Government, in future, have more of a mind for those businesses and people who have been most directly affected by the rules and regulations that the Government have—correctly—felt it necessary to put on to businesses, and not give relief right across the board? We have seen some large supermarkets pay back their business rates, but not all of them. That needs now to be addressed in the future, so that help goes to those who have been most directly affected and suffered the most damage. We do not need, as the leader of the Opposition said yesterday, a council tax freeze across the country, which would affect people who have not had any problems as far as the Covid crisis is concerned.

Lord Agnew of Oulton (Con) [V]: It is right that we should always aim to get the help to the most vulnerable areas, but there is a trade-off between speed of policy announcement and execution and the complexity of creating the sort of flexibility my noble friend refers to. I take on board his comments on the return of the rate rebate by supermarkets. I think a continued public programme to call out any of the larger supermarkets that have not done that will put pressure on them, as most of us are their customers.

Lord Singh of Wimbledon (CB) [V]: My Lords, the Government are to be commended for their furlough schemes and economic packages to mitigate the devastating effects of the Covid pandemic. The Statement rightly acknowledges that things will probably get worse before they get better. Does the Minister agree that, in light of difficulties being experienced by our supermarkets, this applies also to possible benefits from our new economic independence—benefits taken for granted in the Statement?

Lord Agnew of Oulton (Con) [V]: I am not entirely sure what the noble Lord is referring to—perhaps to supply chain issues in the first few days of Brexit. If that is his question, I can assure him that all is being done to iron out these initial problems. Overall, the system has worked remarkably well when one considers the enormous change in operating procedures that businesses have had to bring about on an essentially cliff-edge basis.

Lord Sikka (Lab) [V]: My Lords, the Government have imposed pay freezes on public sector workers, and many others have received little or no financial support and are struggling to survive. However, they face the full and escalating costs of gas, electricity, water, broadband and even the funerals of their loved ones. What consideration have the Government given to freezing prices of these services to enable hard-pressed families to make ends meet?

Lord Agnew of Oulton (Con) [V]: I am not aware of a huge jump in inflation, as suggested by the noble Lord. Indeed, inflation remains extremely low. The pay freeze in the public sector was carefully targeted to ensure that those on the lowest earnings still received some protection.

Lord Razzall (LD) [V]: My Lords, what the Statement does not refer to—although the noble Lord, Lord Balfe, touched on it—is the amount of debt incurred to fund government spending since the start of the pandemic. Government debt is now in excess of £2 trillion, of which nearly 50% has been bought by the Bank of England. Do the Government take the view that the Bank of England can continue to fund significant purchase of government debt, thereby avoiding damaging tax increases so long as inflation and interest rates remain low, or does the Minister think the Government would prefer to return, when they can, to cuts in public spending?

Lord Agnew of Oulton (Con) [V]: My Lords, there is a balancing act here. We all absolutely accept the grave state of the government finances following this crisis, and we will be doing everything we can to bring the books back into balance; however, if that is done too quickly, it will cause greater suffering to those who are most vulnerable, and therefore we have to try to strike a balance. The optimum way out of this will be by economic growth, which is where we are putting a great deal of emphasis.

Lord Lancaster of Kimbolton (Con): My Lords, the £1.4 billion government-backed loan that easyJet announced yesterday demonstrates the perilous state of the aviation sector. Given that a higher tax rate does not always result in increased revenues, is it time to review the air passenger duty, partly to help stimulate demand but also partly, potentially, to increase revenues for the Exchequer?

Lord Agnew of Oulton (Con) [V]: My Lords, the Government are acutely aware of the challenging circumstances aviation is facing. The sector is able to draw on the unprecedented package of measures

announced by the Chancellor, including schemes to raise capital, flexibilities with tax bills and the furlough scheme. The Government have committed to consult on aviation tax reform and will provide an update on the timing of this in due course.

The Earl of Clancarty (CB): My Lords, in answer to a question I asked last week in this House, I was told that the Government were looking at whether the guidance in the Culture Recovery Fund might be changed to enable freelancers to benefit directly, as many freelancers have so far received no support at all. Can the Minister say anything more about this?

Lord Agnew of Oulton (Con) [V]: My Lords, I do not have an update on the response that the noble Earl received last week, but we will of course notify the House as soon as any is issued.

Baroness Blackstone (Ind Lab): My Lords, it is clear that there are gaps in support, with some groups having had no help since the first lockdown began, which can only widen inequality. What is being done to change this and when will more support for these groups be provided?

Lord Agnew of Oulton (Con) [V]: My Lords, we have used such instruments as discretionary funding support for local authorities. We have just given an additional £500 million to enable them to fill gaps, for example, in the small business community, where hardship is being experienced. We remain alert to any other pockets of the economy where we feel we may be able to assist.

Lord Dodds of Duncairn (DUP) [V]: My Lords, the Government's economic measures to get through the pandemic are very welcome but, as has just been said, there are people who have been excluded and their situation needs to be addressed at a national level. In his Statement, the Chancellor also talked of the certainty for businesses as a result of the trade deal with the EU. Unfortunately, it does not look that way in Northern Ireland at the moment, where the detrimental economic effects of the Northern Ireland protocol are all too evident, as we warned. The Government must urgently come to solutions or this will have a big impact on our economic recovery, including invoking article 16 of the Northern Ireland protocol as required, to smooth the way for frictionless trade and commerce to continue between Great Britain and Northern Ireland. Can the Minister update your Lordships' House on steps that will be taken in the coming days to fulfil the promises made by the Prime Minister on this issue?

Lord Agnew of Oulton (Con) [V]: The Government do not accept that the approach the noble Lord is suggesting is the right one. We have put in place the trader support scheme in Northern Ireland, which I had some responsibility for; some 28,000 businesses have registered for it, including more than 12,500 in Northern Ireland, and 23,000 of those are in a ready-to-trade state. Only last weekend, we managed to move 1,000 lorries across from GB into Northern Ireland; that was after the end of the in-flight concession, which was a big concession, essentially saying that goods were already in transit out of the EU at the point of delivery into Northern Ireland. That has worked smoothly. We will, of course, see problems over the next few weeks as people adjust to a very new system, but I am confident that we will be able to reduce the friction substantially over the weeks and months ahead.

Lord Lilley (Con): My Lords, one lesson of the pandemic is that in a crisis, government bodies, from the MRHA authorising vaccines to local authorities authorising pavement cafes, can take decisions in a fraction of the time they used to. Given the importance of encouraging the growth of existing businesses and the creation of new ones, will my noble friend put pressure on all government bodies to accelerate decision-making, by requiring them to publish the times they take to make decisions and by setting times after which approval will automatically be deemed to be given?

Lord Agnew of Oulton (Con) [V]: I very strongly support my noble friend's views on this. We have seen some remarkable decision-making across government over the last few months, at a much faster rate than normal, and I encourage my noble friend to keep up his campaign to remind people of what is possible. In my own oversight of HMRC border-readiness, I used a simple mantra, which is that it does not take any longer to make a decision than not to make a decision, and it was remarkable how quickly decisions were made. I hope very much that we can continue with that philosophy.

Lord Loomba (CB) [V]: My Lords, I welcome the Chancellor's timely update on our economy and the large amount of support he has given to businesses across all sectors throughout the country. As we are all too aware, we have a challenging time ahead balancing the books. Can the Minister say what steps are being taken to ensure that businesses inappropriately claiming financial assistance pay it back?

Lord Agnew of Oulton (Con) [V]: We are aware of the possibility of wrongdoing by businesses and the claiming of grants that were not legitimately theirs but, as I said on an earlier question, the priority was to get the money out quickly to the overwhelming numbers of people who deserved it. Some 1.4 million bounce-back loans were approved, worth over £43 billion; on CBILS, there were 82,000 loans worth £19 billion. There will undoubtedly have been wrongdoing in that. I assure the noble Lord that we are active in our efforts to clamp down on any wrongdoing.

Lord Berkeley (Lab) [V]: My Lords, I live in the Isles of Scilly. We were very grateful for the support the Government gave to the lifeline services to the mainland in the first lockdown, but now, apparently, nothing is available to keep them going during winter. We are at risk of companies having to stop services, and we will have no freight and very few passengers.

[Lord Berkeley]
Can the Government explain why they have not given any more support to these companies? Or will they wait until they go bust, and then what will they do?

Lord Agnew of Oulton (Con) [V]: My Lords, we expect to provide over £3 billion-worth of support to local authorities over the next year, on top of the support we have already given. For example, over Christmas we provided the £1,000 Christmas support payment to wet-led pubs in tiers that were subject to lockdown. I feel the noble Lord might be being a little harsh; there has been a great deal of intervention to support local authorities and small businesses.

Lord Flight (Con) [V]: My Lords, I congratulate the Government and the Treasury on a remarkably quick response through very large programmes of financing. I have a simple question: we see different figures of the impact on the economy, but what was the net UK economy contraction during the calendar year 2020 and what is the forecast contraction for the calendar year 2021?

Lord Agnew of Oulton (Con) [V]: My Lords, I do not have those figures to hand, but there will be ongoing economic Statements and my right honourable friend the Chancellor will address this in his Budget in a few weeks' time. It is perhaps worth pointing out international comparisons; the way the ONS uses data here has had a detrimental impact on how it has reported on the shrinkage of our economy, because it considers outputs instead of inputs on things such as the salaries of teachers and other civil servants, who were not necessarily working because of the crisis but were still being paid. There will be more information on this, particularly in the Budget.

Viscount Waverley (CB): My Lords, noting the expected but regrettable economic downturn, is it not excellent economic news that Unite has suspended strike action at Rolls-Royce at Barnoldswick, saving 350 jobs? Hurrah to that. But how will the Government address the challenge, talking more in UK terms rather than taking a four-separate-nations approach, of how we will unite the four kingdoms to speak with one voice on economic priorities and an implementation strategy?

Lord Agnew of Oulton (Con) [V]: I share the noble Viscount's view that we need to talk more of a single nation. I fear we will hear more of this up to the devolved elections over the next few months, but I hope that, after that, we can get back to speaking more as a single country.

Lord Moynihan (Con) [V]: My Lords, I welcome the £4.6 billion in grants announced for the retail, hospitality and leisure sectors, as well as the sports winter survival loan package of last November, which covered 11 major spectator sports. Will my noble friend ask his colleagues to turn their attention to the community sports and recreation sector, whose clubs and community centres are currently on their knees, so that, when safe, they can be opened up as soon as possible, to enhance the physical and mental health of the nation, with at least some financial oxygen in essential life-support grants and loans?

Lord Agnew of Oulton (Con) [V]: I share the noble Lord's concern about all these institutions that have been forced to shut down. We all very much look forward to the moment when they can reopen, which is why so much emphasis is being placed on the rapid rollout of the vaccine.

Lord Empey (UUP) [V]: My noble friend has referred to the economic difficulties Northern Ireland will face being separated in some way from its principal single market. However, the biggest challenge we face here is that his right honourable friend the Secretary of State announced a few days ago to the world that there was no border in the Irish Sea. This provoked a response of ridicule and anger in equal measure. How can we start a recovery if our representative in the Cabinet cannot even admit the practical situation that businesspeople face every day? Can my noble friend prevail on him at least to acknowledge the realities on the ground?

Lord Agnew of Oulton (Con) [V]: My noble friend raises important points. As I mentioned earlier, we are a few days into an enormous change in how trade operates across GB and the EU, and across GB and NI, but I reiterate the Government's absolute commitment to keep the friction between GB and NI to an absolute minimum. We are doing everything we can to do that. I ask my noble friend to bear with us, because there will be a learning process over the next few weeks.

Baroness McIntosh of Pickering (Con) [V]: My Lords, the night-time economy contributes, in its heyday, over £66 billion per annum in revenue and employs 8% of the workforce—a disproportionate number of whom are young people, helping motivate them and often launching them on a career. Will my noble friend look carefully at what specific long-term help can be given to all businesses in the night-time economy, not just bars, nightclubs, restaurants and street vendors but also those that advise them—marketing companies, record labels, agents, managers, PR companies, taxicabs and newsagents—to enable those which are not facing ruin in the meantime to bounce back sustainably?

Lord Agnew of Oulton (Con) [V]: The noble Baroness raises a very important point. I share her concern for this sector because, as she quite rightly says, it is not just about bars and clubs but our cultural heartland—theatres and everything that goes with it. I reassure her that this is very much on the Government's mind and will be addressed as we come out of this crisis.

Baroness Altmann (Con) [V]: My Lords, I congratulate the Government on their rapid reactions but reiterate my concerns about relying so much on debt and QE to try to sustain growth. Given the extraordinary widening of wealth inequality entailed by QE asset purchases, disadvantaging the poorer, younger citizens, would the Government welcome the Bank the England now considering a people's QE when creating further additional

funds to boost growth directly, as well as contributing to levelling up rather than continuing to distort capital markets, undermine pension funding and help the wealthiest?

Lord Agnew of Oulton (Con) [V]: The noble Baroness will know that the Government are not in favour of a people's QE. The QE that has happened this year has been more effective than the QE in the 2008-09 crisis; at least in this situation the money has gone directly into our economy to solve and help the problem, whereas in 2008-09, as far as anyone has ever been able to explain it to me, at least half the money left the country. We are learning, but there is a great deal of nervousness about something such as a people's QE, because being able to print money without any comeback is almost too good to be true. Indeed, at the weekend, I bought a book by Ray Dalio on debt crises in history to try to understand more about this, because I feel we need to be very cautious about borrowing more and more money.

The Deputy Speaker (Baroness Garden of Frognal) (LD): My Lords, the time allowed for this Statement has now elapsed. I apologise to the noble Lords, Lord Walney and Lord Holmes of Richmond, that we did not have time for their questions.

Arrangement of Business

Announcement

2.01 pm

The Deputy Speaker (Baroness Henig) (Lab): We now come to the Report stage of 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. 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. We will now begin.

Medicines and Medical Devices Bill

Report (1st Day)

2.03 pm

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

Amendment 1

Moved by ***Lord Bethell***

1: Before Clause 1, insert the following new Clause—

"PART A1

THE COMMISSIONER FOR PATIENT SAFETY

Establishment and core duties etc

(1) The Secretary of State must appoint a Commissioner for Patient Safety (referred to in this Part as "the Commissioner") to exercise the functions set out in this Part in relation to England.

(2) The Commissioner's core duties are to—

(a) promote the safety of patients with regard to the use of medicines and medical devices, and

(b) promote the importance of the views of patients and other members of the public in relation to the safety of medicines and medical devices.

(3) The Commissioner is not to be regarded as the servant or agent of the Crown or as enjoying any status, immunity or privilege of the Crown.

(4) Schedule (Further provision about the Commissioner for Patient Safety) makes further provision about the Commissioner."

Member's explanatory statement

This amendment inserts a new Clause which provides for the creation and core duties of a Commissioner for Patient Safety in relation to medicines and medical devices in England. The new Clause and the Schedule which it introduces would form a new Part, to appear before Part 1.

The Parliamentary Under-Secretary of State, Department of Health and Social Care (Lord Bethell): My Lords, patient safety is very much at the heart of the Bill, and while we have an enormous amount to get through this afternoon, I beg the Chamber's forbearance if I talk in some detail about this extremely important amendment. Patient safety is the golden thread that runs through this entire Bill. Safety has been our guiding force in amendments that have made it to the Bill, from the changes to decision-making on regulatory change and the new safety lock amendment—which we will debate later—to the enforcement powers for medical devices to make clearer what the MHRA can do to take action, through to the medical devices information system.

The Government have heard the calls, including the strong cross-party support, to establish an independent patient safety commissioner for the health service in England. Of course, this was the centrepiece recommendation of the Independent Medicines and Medical Devices Safety Review helmed by my noble friend Lady Cumberlege, to whom I pay profound tribute for her tireless championing on behalf of patients. I am delighted that Amendment 1 in my name—with which it is convenient to debate Amendments 54, 65, 70 to 72, 74, 86, 87, 91, 95 and 97—delivered upon that recommendation. These amendments provide for an independent advocate to champion the safety of patients. The patient safety commissioner will promote their interests and those of other members of the public in relation to the safety of medicines and medical devices.

We acknowledge that the patient's voice can advance safe care and system improvements but that it needs to be strengthened, as explained in my noble friend's

[Lord Bethell]
review published six months ago. Listening to patients is central to preventing the kinds of issues which that review brought so clearly into focus. If we do not strive to listen to patients, their families and to staff, we limit our ability to learn from mistakes, be innovative and continually improve. I pay testament to the extensive listening and the passionate advocating by my noble friend, her supporters and all patient groups.

Patient safety is a system-wide concern. It cannot be tackled by a single individual but needs to be rooted in all the branches of our health system. Good progress has been made: for example, we are improving system-wide learning through measures such as the Healthcare Safety Investigation Branch and the implementation of the 2019 NHS Patient Safety Strategy with our National Director of Patient Safety, Dr Aidan Fowler, in charge. That strategy has been listening to patients.

Staff are also encouraged and protected to speak up if they have concerns about anything they believe is harming the services their organisations deliver or commission. They are supported by the NHS People Plan, which envisages a health service that is compassionate and inclusive, not hierarchical, and where staff are listened to. The Government's emphasis on patient safety will also be reinforced by the establishment of a new patient safety programme board. The board will take an overview—with pace and rigour—of measures and actions across the health system to improve patient safety.

The Government fully support sharpening our focus on the safety of NHS-funded services to patients and the public. We accept that the patient safety system needs to get better at identifying issues and listening to patients' experiences of avoidable harm. Better co-ordination across and between regulators and other oversight bodies is also needed.

A patient safety commissioner will help us to champion the views of people who have been harmed by treatments provided by the health service. He or she would reinforce a culture of humility, openness and learning. The role is essentially about prioritising the insights of patients as a vital source of learning.

The Government's amendment puts this new part of the Bill first. Amendment 1 provides for the appointment by the Secretary of State of a patient safety commissioner who is an independent statutory officeholder funded by the Department of Health and Social Care. It sets out the commissioner's core duties, which are to promote both the safety of patients and the importance of ensuring that they are heard.

Patient engagement will be integral to the role of the commissioner. Proposed new Schedule A1 outlines the ways in which the commissioner must inform, consult and involve patients. This will ensure that patients' concerns are being heard and that the work of the commissioner has focus and relevance for the people he or she is being set up to serve.

We have reflected carefully on the patient safety commissioner model set out by my noble friend's comprehensive report. We agree on the importance of the commissioner's role; it is a critical new part of the map of patient safety. But there are other areas of significant importance to the Government. The commissioner is one part of the whole system—the fundamental change that it required to tackle unsafe care and empower patients. A step change is required in how the health service transforms itself in a joined-up way to put patient safety at its core. Significantly, the introduction of the commissioner should not create overlap or confusion within that health service architecture, thereby reducing the potential to deliver patient safety improvements for patients. Indeed, my noble friend's report rightly made it clear that the duplication of the roles of other regulatory bodies should be avoided.

In view of this, the patient safety commissioner will not act as an ombudsman. He or she will not carry out functions in pursuit of specific cases. But they can consider individual cases in their role as an overarching advocate for all patients and of making thematic and systemic recommendations. These areas are where we believe the commissioner can have greatest impact.

We have also given the patient safety commissioner deliberately intrusive powers, as called for by my noble friend Lady Cumberlege. He or she will be empowered to request and share information from relevant public authorities or a "relevant person", meaning anyone providing health care, in relation to medicines and medical devices in England. The commissioner's ambit will cover both the public and the independent sector.

Where my noble friend and I differ is on the process of the appointment and sponsorship of the commissioner. The patient safety commissioner will be appointed by the Secretary of State for Health and Social Care and funded by the Department of Health and Social Care. It is absolutely right that this should be the case. For example, the Secretary of State is able to initiate action on reports and understands, and has strategic oversight of, the system the commissioner is looking at.

Some noble Lords have expressed concerns about how such a commissioner might maintain their independence, but I believe that such concerns are unfounded. I am encouraged by the precedent of the Office of the Children's Commissioner, which drew praise from several noble Lords in Grand Committee for its independence. As noble Lords know, the Children's Commissioner is sponsored by the Department for Education and guards its independence very well. The Victims' Commissioner does exactly the same and is sponsored by the Ministry of Justice.

It is critical—that is agreed—that the patient safety commissioner is able to speak out without fear or favour. He or she must have the powers and functions to act independently to maximise their impact and confidence. That is absolutely the case here. It is also critical that the right calibre individual with a strong voice for patients is appointed to the role. I do not think any such person would accept such a role if they felt they would in any way be constrained in that role. Nor do I think they would remain silent. Furthermore, we would expect the Secretary of State to work with the commissioner to establish how they will safeguard and secure the commissioner's independence. Independence is not static but an active objective, which we would expect the patient safety commissioner to be prepared to approach continuously.

The commissioner will have the power to make reports to both the public sector and independent sector, and to the Department of Health and Social Care if they so wish. Those reports are entirely independent. There is no intention—and indeed no restriction—that would allow for the Secretary of State to edit those reports. As an independent public appointee, the commissioner will also be subject to the scrutiny of Parliament, including through the Health and Social Care Select Committee.

The powers in the Bill are accompanied by a regulation-making power about the terms of office of the patient safety commissioner, the appointment of staff, and other operational matters. But while this power is exercised by the Secretary of State, we are not proposing that the Secretary of State would have any power over the commissioner regarding the fulfilment of his or her functions. However, it is right that the detail is left to regulations so that we can publicly consult on this, as we are obliged to do so under Clause 45. It is important that we get the details right. That is also why the regulations will be subject to the draft affirmative procedure.

Other amendments make minor changes to ensure that the patient safety commissioner clauses work well with the rest of the Bill.

From the *First Do No Harm* report by my noble friend Lady Cumberlege, to earlier, well-known inquiries and investigations, we have heard numerous harrowing stories with terrible examples of how patients have been let down badly by our most loved institutions. As noble Lords have said, now is the time to act. The Government have listened to the impassioned and compelling arguments from all sides, and I thank my esteemed colleagues for their help in shaping this amendment.

We have no doubt that restoring patient trust will be at the heart of the patient safety commissioner's role and that he or she will advance patient safety. Our commitment to amplifying and acting on the voices of patients in our health service is paramount. To that end, I beg to move.

Baroness Cumberlege (Con) [V]: My Lords, I thank the Minister for his huge support throughout this whole process—all the times we have had to meet and I have met with his officials. I also thank him for the way in which he has so comprehensively introduced his amendment today. To be honest—"O ye of little faith!"—there were times when I thought the patient safety commissioner would not see the light of day. However, I underestimated my noble friend and thank him for agreeing to the concept and for bringing it to fruition with his officials.

2.15 pm

I am very much aware of the long hours and prodigious amount of work that has gone into this amendment. I and many others are truly grateful, not least of course to my fellow parliamentarians, who have been stalwart in their support, but perhaps more importantly to all the patients and their families, who have endured the most appalling experiences over very many decades, and who have fought hard to see this day dawn.

In the report of my review, I and my small team recognised that we did not need another regulator. Many of those parts of the NHS and the healthcare system have regulators, but we did not want another regulator—we have those in plenty. We wanted something —or rather someone—new, who would be pivotal to improving patients' safety and to prevent avoidable harm in the future. My noble friend really understands that. We need a listener, an advocate and a person of standing, who would call the healthcare system to account when needed.

In my letter to the Secretary of State, I said that the new patient safety commissioner would be the golden thread that would tie our disjointed healthcare system together for the benefit of those who matter most—the patients. I know, having listened to the Minister on many occasions and this morning, that he fully understands that. I am therefore delighted and grateful, and I thank the Government for having listened and agreed with me and my team. This new clause and the new schedule are so wonderful to see. I cannot thank my noble friend enough for his personal commitment to making this all happen. As I have said, I know a whole team has worked very hard alongside him, including other Ministers and of course his officials. I thank all of them from the bottom of my heart.

The Government's amendments reflect crucial elements set out in our report: for example, the need for the patient safety commissioner to be independent. I hear what the Minister has said today, but we still need some reassurance on that. The patient safety commissioner cannot work or be effective if he or she is not independent. We are also very pleased that the patient safety principles underpin the commissioner's work—that has been set out very clearly today and on other occasions—and of course, always, that patients will be closely involved in all that work. There is also an obligation on the system to respond to and co-operate with the commissioner. That is absolutely critical and is now in statute, and I thank those who enabled that to happen.

Having met so many people who have suffered avoidable harm and listened to their concerns, I know that the creation of a patient safety commissioner will mean a huge amount to them. One thing we heard so often from many them was the phrase, "Please don't let this happen to anyone else", a selfless plea that we should act to stop harm happening to other people in the future. Today, we are doing that. The patient safety commissioner him or herself will do just that, and I hope that will at least bring some peace of mind to those who are suffering now.

As my noble friend is aware, I have three points on which I would welcome some further reassurance. First, the importance of the role dictates that we must act as swiftly as possible to establish this role and this person in their job. The Government must of course have a credible selection process. I understand and welcome that; however, I know that my noble friend appreciates the urgency and there will be considerable pressure from patient groups and parliamentarians if we do not act at speed. This is not the time to dally. We must not risk losing the trust placed in us to get this person in post, up and running.

It is unclear to me whether the appointment of the patient safety commissioner will be independent of, and separate from, the much broader and lengthier

[Baroness Cumberlege]
public consultation and making of regulations. These regulations may determine some of the commissioner's terms of office and how that person should operate. In my view, it is imperative that the two are kept separate—not least because this will facilitate the early appointment of the commissioner, who can then properly influence and shape those regulations. There is a precedent for this with the appointment of the designate domestic abuse commissioner. I see no reason for delay and would welcome my noble friend's assurance that this appointment will be made with express urgency. I am sure the Minister will agree that we want a high-speed train, not a rumbling steam engine.

My second point concerns the definition of "relevant persons". As I understand it, "relevant persons" will include healthcare providers in England and bodies exercising public functions relating to medicines and medical devices, but I am concerned that that does not go far enough. Other public bodies may have relevant information that could and should usefully inform the commissioner's signal detection activities—opportunities to look wider than the norm and to scan the horizon. I include in this group, for example, the coroners' courts, where cause of death may be found to be attributable to a medicine or medical device. I should be grateful if my noble friend could clarify whether the phrase "relevant persons" may include any public body that has information relevant to the duties of the patient safety commissioner.

I am also concerned about information of relevance to the commissioner that is held by manufacturers of medicines and medical devices. I know from my review that not all information from clinical trials, in particular, is published and shared with regulators. I should be grateful if my noble friend could reassure me that manufacturers will be required to share information and co-operate with the commissioner. Does he agree that it would be appropriate to place a duty to co-operate with the commissioner on manufacturers as a condition of selling to the UK market?

In evidence to the review, Professor Carl Heneghan repeated a question:

"Is the whole system commercially conflicted? Yes it is",

he replied. In last week's *BMJ*, Sir Cyril Chantler, vice-chairman to the review, recalled that a

"constant voice across the country was of patients telling us they felt the mesh had been commercially promoted and doctors were receiving benefits from companies prescribing it."

Does the Minister agree that it would be appropriate to place a duty to co-operate with the commissioner on manufacturers, as a condition of selling to the UK market?

My third point concerns the following phrase in paragraph 3(3) of the Schedule:

"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."

It is those five words—

"so far as reasonably practicable"—

that provide the reluctant person or organisation a get-out, not to co-operate with the commissioner. I am concerned that the words

"so far as reasonably practicable"

provide too much wriggle-room to the organisation from which the patient safety commissioner has requested information. The Freedom of Information Act requires the holder of the information to reply within 20 working days. I am not requesting anything so specific, but simply that we should not give the holder of information an opportunity to evade their responsibility when the words of the schedule require the commissioner to be reasonable in his or her request. There should be parity on that.

The commissioner must be in control. As currently drafted, it rests on the commissioner to have to challenge the relevant person's reason for noncompliance. This could be a crucial waste of time if the information could prevent serious harm. I appreciate that the phrase exists elsewhere in legislation and its use here is not considered unusual. It is said that the commissioner should go to the lengths of naming and shaming. I do not think naming and shaming is a good solution. It is a distraction, a further waste of time and requires publicity and input from the media, which be against the commissioner's whole raison d'être and what he or she is trying to do.

I add finally on this that those of us who were, or are employers, marvel at the fertile imagination of individuals and organisations intent on hiding some inconvenient truth, and we came across a lot of that in our review. Timely information is so important. It is crucial, because information is power, and we should not encourage a get-out in the schedule for those who still wish to hide things. It is a very small ask, but I should be grateful if my noble friend would consider omitting just those five words from the schedule prior to Third Reading.

In conclusion, it strikes me that one of the qualities of good government and good leadership, as in so many walks of life, is the willingness to listen. As we found during the review, that is not something that the healthcare system does well. When we listened to the women, they said, without fail, "Thank you for listening. You are the first people who really have listened". This time, the Government have listened and, above all, acted. They have been inordinately patient with me and have listened to me and to my team and, more importantly, to so many people who have suffered and who want there to be a patient safety commissioner. I am truly grateful.

2.30 pm

Lord Patel (CB) [V]: My Lords, I shall be extremely brief. It was a pleasure to support the noble Baroness, Lady Cumberlege, and I congratulate her on achieving a remarkable feat of getting patient safety in statute for the first time in the United Kingdom. Her tenacity was such that she was never going to give up. I also congratulate the Minister. He obviously listened and understood all the arguments that were made. He has produced the establishment of an independent patient safety commissioner. Having been concerned with patient safety for many years, it is good to know that for the first time it is in statute. The noble Baroness made a few important points that were well argued as to why words may be misinterpreted. I hope that the Minister has listened and will respond positively. Again, I congratulate her—it was a pleasure to support her.

Lord Hunt of Kings Heath (Lab) [V]: My Lords, I, too, welcome the Government's amendment establishing the patient safety commissioner. This is highly significant and a great tribute to the noble Baroness, Lady Cumberlege, and her team. I should also declare an interest I must declare an interest as a member of the GMC board.

The noble Baroness's report, *First Do No Harm*, is a stark and moving account of how thousands of patients were let down in a serious and life-changing way. I go back to her report because she found that the healthcare system, in which she included the NHS, private providers, regulators, professional bodies, and pharmaceutical and device manufacturers, was disjointed, siloed, unresponsive and defensive. It does not adequately recognise that patients are its raison d'être. Those are telling points, which led the noble Baroness to recommend the appointment of a patient safety commissioner, an independent and proactive public leader with a statutory responsibility to champion the value of listening to patients and promoting users' perspectives in seeking improvements to patient safety. That is welcome and it will be essential that the person who is appointed is robust, fearless and commands wide respect. Their independence needs to be assured. I hope also that the appointment will be subject to Select Committee scrutiny and I should be glad if the Minister can comment on that.

Picking up on a point that the noble Baroness made, I should also be grateful if I could have a little more explanation about what is meant by relevant bodies, as defined in the schedule. It is clearly important that bodies with responsibilities in relation to patient safety are expected to respond to a report or recommendation made by the commissioner. Can the Minister give a broad indication of the relevant bodies? Also, in relation to the private health sector, my reading is that this is covered by the Bill and that the schedule provides for that. Can the Minister respond?

Overall, however, I commend the Minister on the Government's response to this significant recommendation by the noble Baroness, Lady Cumberlege.

Baroness Finlay of Llandaff (CB) [V]: My Lords, these amendments are a testament to the incredibly hard work and perseverance of the noble Baroness, Lady Cumberlege, the Minister and the noble Baroness, Lady Penn. They have all worked hard to get to this point. The report, *First Do No Harm*, must be a turning point in driving up better outcomes.

I hope that in the response to these proposals it will be helpful to have reassurance that the new post will be adequately resourced, the timeframe for fulfilling the appointment is rapid, and, subsequently, regulatory requirements can be defined and relevant statutory instruments drawn up. The independence of the post-holder is crucial. The person must be able to work across all the different and varied organisations and structures that have responsibility for patients, directly or indirectly. That will require promotion to all organisations that they have a duty to co-operate and collaborate with the commissioner to ensure that early warning signals are picked up and heeded through processes that are light on bureaucracy yet rapidly responsive in order to pick up signals. We cannot have years of accumulation of distressed patients. When things start not to be right, those amber warning lights must start flashing.

I urge the Minister to ensure that the remit of the commissioner is as wide as possible. For example, the coroners' reports that the noble Baroness, Lady Cumberlege, referred to have not had adequate enforcement by others sometimes. The reports made powerful recommendations but it was found that those responsible for enforcing them have been so slow to act that the proposals have effectively gathered dust.

In previous debates, I raised the need for the yellow card scheme to be updated—opened for easy use by patients themselves, who may wish to report adverse outcomes. The wording of the Bill that I found most helpful and welcome is the part stating that the role

"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".

Can the Minister make sure that the reporting mechanisms are open to patients and do not hit a hurdle when they try to report to a clinician who does not recognise the full import of they are saying?

To conclude, I reiterate my congratulations to all, particularly the noble Baroness, Lady Cumberlege, and her team, and look forward to the next phase of working with her and others as this important development moves forwards.

Lord O'Shaughnessy (Con): My Lords, I join other noble Lords in expressing my sincere thanks to my noble friend the Minister for the progress that we have made. In all fairness to him, he said that since Second Reading he was listening, but we all know that it is sometimes possible to listen and not hear, let alone act. On this occasion, he heard and acted. I join other noble Lords in expressing my sincere gratitude for that.

I also pay tribute to my noble friend Lady Cumberlege. No one doubted her tenacity but it has been on display in bucketloads, and she has made the progress that her superb report deserves. More than anyone, I pay thanks to the army of campaigners; many of us have met them, and they could not help but move us with their stories. This legislation is ultimately for them and a tribute to them.

I had a close look at my noble friend the Minister's amendment and compared it to that of my noble friend Lady Cumberlege. Clearly, there is a specific issue about where the organisation, the commissioner, should sit, but there is a precedent for doing that in the way in which the Minister suggested. I take confidence from his determination to give proper independence to the role. A lot will depend on the kind of person recruited, how they are recruited and to whom they are accountable. I should like him to say a little more about how he envisages that happening.

We also need to hear more detail on the timetable. The Minister will know that when one makes big commitments of this kind, they are staging posts—never the destination. There is still some way to go in making sure that we get there quickly. That is important, as my noble friend pointed out. However, the powers in the amendment are important to recognise. On the ability

[Lord O'Shaughnessy]
to demand information from relevant persons, as other noble Lords have said, we need to hear a little more about who they are and the consequences of non-compliance. However, they are powerful ways in which the commissioner can act and create change in the system. I have no doubt that they will be effective.

In conclusion, I make a couple of comments provided by the ABPI's briefing. They relate to further questions around the nature of the relationship between the commissioner and the MHRA and other bodies, how the four nations of the UK will act together on patient safety, given that we are a single market, and ensuring diversity of patient voice.

I would also add one more thing to that. Patient safety is not just about finding out when medicines and devices go wrong; it is also about access to them. Will the patient commissioner have a remit to investigate these kinds of issues?

However, these questions are for tomorrow. Today, we want to recognise the progress that has been made and the amendments put down in the name of my noble friend. I thank him sincerely for them and I thank my noble friend Lady Cumberlege for her dedication to this particular cause.

Baroness McIntosh of Pickering (Con) [V]: My Lords, I, too, add my congratulations to my noble friend the Minister and pay particular tribute to the tireless work of my noble friend Lady Cumberlege in bringing us this far. I welcome government Amendments 1 and 54.

I want to take this opportunity to mention two specific issues that we focused on in Committee and seek confirmation on where we are in this regard. I want in particular to look at the right of patients to report directly on their own experience, rather than waiting for the patient safety commissioner to investigate. I would welcome hearing that my noble friend the Minister imagines that the commissioner should have this power. If not, would he consider introducing such a measure at the first available opportunity? It is so important that the voice of patients is heard. I remember the accounts that my noble friend Lady Cumberlege gave in Committee of her work and that of her team in producing the report, *First Do No Harm*; that will be a lasting legacy. Allowing patients the right to report directly, without necessarily waiting to be asked, would cut through many of the difficulties with medicines and medical devices, and would enable the patient safety commissioner to report directly to the Government in this regard.

The only other point that I wish to make at this stage is that of the regulations that my noble friend envisages in the government amendments in this group. Can he confirm that these will be discussed and agreed with the devolved Administrations at the earliest possible stage? Can my noble friend assure us that if the devolved Administrations raise any significant issues or highlight any problems that they have with the draft regulations, these will be acted on before the regulations are adopted and sent to each House of Parliament?

We are in a very good place. I congratulate my noble friend Lady Cumberlege and her team on bringing us here, and I pay special tribute to my noble friend the Minister for listening to the concerns of so many people, over so many years, to bring us to where we are today. I wish the amendments godspeed.

Baroness Bennett of Manor Castle (GP) [V]: My Lords, I join the universal commendations for the Government for accepting the recommendation to introduce a patient safety commissioner. It demonstrates that campaigning can work for everybody, from school pupils to Premiership footballers to Members of the House of Lords—in this case supported by patients, many of them suffering from continuing illness and disability.

I want briefly to pick up three points made by the noble Baroness, Lady Cumberlege. The first is the importance of the commissioner being a person of standing. As the noble Baroness's report clearly explains, there is a strong gender aspect to the fact that far too many patients have not been listened to, have been ignored and have been mistreated by the system. It is really important that the patient safety commissioner is well equipped to understand that and make themself accessible to all patients. As the noble Baroness said, it is clear that the patient safety commissioner should be a person of standing and the kind of person who should shape the role that they will ultimately fulfil.

That brings me to my second point, which the noble Baroness and many others have stressed: the urgency of this appointment. As has already been pointed out, the Domestic Abuse Commissioner has been appointed before we have even passed the Domestic Abuse Bill. That is very much a model. I have a direct question for the Minister. It should not be beyond the capacity of the department to advertise this role within, say, one month. If he does not think that this timetable is reasonable, can he suggest what he thinks a reasonable timetable is? The noble Lord, Lord O'Shaughnessy, also asked this. I also echo the point made by the noble Lord, Lord Hunt of Kings Heath, that it is crucial that this appointment has Select Committee scrutiny.

2.45 pm

Thirdly, I very much agree with the noble Baroness, Lady Cumberlege, that naming and shaming is not the way forward. The commissioner needs to be able to get urgent action; that certainly has not worked very well with the enforcement of minimum wage legislation. The commissioner needs to be able to swing into action.

Finally, I want to pick up a point made by the Minister in his introduction. He made a comparison to the Children's Commissioner, saying that that commissioner is also appointed by the Secretary of State and funded by the department. There is a fundamental difference between the Children's Commissioner and a patient safety commissioner. The Children's Commissioner has a very broad remit, of course, and has done excellent work on everything from immigration law to poverty and inequality—things that the department itself might well want to see action on, as part of bringing its entire weight to assisting children suffering so many disadvantages to get an education. But that is not quite parallel to the patient safety commissioner operating in the health department and within the NHS framework. That is where such a comparison does not quite work.

Baroness Ritchie of Downpatrick (Non-Afl) [V]: My Lords, I am delighted to follow the noble Baroness, Lady Bennett of Manor Castle.

At this stage, let me congratulate the noble Baroness, Lady Cumberlege, on her thought-provoking report, *First Do No Harm*, which really led to the position we are in today. I also thank the Minister—the noble Lord, Lord Bethell—for bringing forward on Report this amendment regarding the patient safety commissioner and putting it on a statutory basis. Led by the noble Baronesses, Lady Cumberlege and Lady Thornton, we have had several meetings with the Minister on this particular issue. He gave commitments in this respect, for which I, for one, am particularly grateful.

Naturally, as with everything, I have some questions, to which I and others would like some answers. On the nature of the patient safety commissioner's appointment, how independent will they be? They will be accountable to the Secretary of State for Health and the department, but what does that level of accountability mean? What will the nature of the regulations circumscribing the appointment be? When will the appointment actually take place? What is the timeframe? Will there be adequate resources on an ongoing annual basis to fund this position, to ensure that the patient safety commissioner can act as an advocate on behalf of patients?

We have heard what the Minister had to say: that patient safety is the golden thread holding this Bill together. That is particularly important, but the patient safety commissioner will be the person who will have to provide direction and leadership. This was one of the principal aims and outcomes of the report by the noble Baroness, Lady Cumberlege, *First Do No Harm*. Patients who have been unwell and feel that they have been slighted or undermined in their dealings with medical practitioners want to feel safe and have confidence that they are being listened to. I hope that, whenever the regulations are published and enacted, this appointment can take place at very short notice. And, of course, the commissioner must be someone who commands respect and is a person of standing.

It is vital that the commissioner leads, with full patient group engagement and involvement, on the development of a set of principles for better patient safety that governs the way the commissioner fulfils his or her remit. I am delighted to support the government amendment. It goes without saying that I also support Amendment 65 in the name of the noble Baroness, Lady Cumberlege. There are issues with who the person is accountable to—the Department of Health, in this instance. I know that the noble Baroness was looking for the Cabinet Office, but that is just a detail. We have arrived at an important stage today, and I welcome that.

Finally, I have been talking to the Minister at the meetings organised by the department with the noble Baroness, Lady Cumberlege, to give an update on Northern Ireland, where there are several ongoing inquiries. The Minister and his officials were very helpful and are having discussions with the Minister for Health in Northern Ireland. Maybe today the Minister could provide me and your Lordships' House with an update on the position within the Northern Ireland Executive and Department of Health.

Lord Lansley (Con) [V]: My Lords, I am pleased to follow the noble Baroness, Lady Ritchie of Downpatrick, who asked some good questions. Indeed, many noble Lords have asked good questions about the functioning of a patient safety commissioner. All are agreed that we have come very far, very quickly, and the Minister and my noble friend Lady Cumberlege are to be congratulated on having brought this proposal from her excellent report to primary legislation so rapidly. Knowing how difficult it is, I commend the Minister and his team for securing collective agreement to such a significant policy innovation so rapidly, to the point that we can put it into the Bill on Report.

I want to make two points. First, as I know from the past, independence can be instrumental to the functioning of an organisation, but the NHS can, if one is not careful, see independence as something outside the system. It is somewhat discounted because of that. We must always think of the patient safety commissioner in two important respects. First, it should be not only independent but influential. A number of noble Lords have spoken about how that might best be achieved. That influence is terrifically important.

Secondly, patient safety is central across the NHS and is regarded as such. As the Minister and the noble Lord, Lord Patel, evidenced, we have come a long way with safety in the NHS—for example, in the reduction in healthcare-acquired infections. I was responsible for introducing never events and a range of other factors. Mainstreaming safety to become a central concern of commissioners and providers across the NHS has been a recurring feature of the work of this Government and their predecessors, and of my successors, Jeremy Hunt in particular.

I stress that that work on safety inside the NHS is clinically led and data-driven. The patient safety commissioner has a remit focused on hearing from, understanding and working with patients. That distinction is tremendously important and must be made clear to all those working across the health and care systems, from the outset. There is something new and distinctive about the patient safety commissioner, and it is not simply another accretion to the many organisations that those who work in the health system feel impede their lives. On the contrary, this is a representative of patients who, by virtue of that, attracts special attention from their point of view and brings a distinctive and unique voice into the NHS systems. I am pleased to have had this opportunity to say those few things and to support the government amendment in the name of the Minister.

Baroness Masham of Ilton (CB) [V]: My Lords, I agree with the noble Lord, Lord Lansley. It is very good news that there is to be a patient safety commissioner. I congratulate everyone who has worked so hard to create this amendment, especially the noble Baroness, Lady Cumberlege. It is so good that the Government have listened. Patient safety is vital, especially now when the NHS is under so much stress and demand. Over the years, some tragic incidents could have been avoided if patients had been listened to and there had not been cover-ups.

The noble Baroness feels that the words

"so far as reasonably practicable"

[Baroness Masham of Ilton]
should be removed. She may feel that they would weaken the amendment; is this the case? This is important, because patients need clear information about how they are to communicate with the patient commissioner, so that they trust the system.

Baroness Watkins of Tavistock (CB) [V]: My Lords, I am delighted to follow my noble friend Lady Masham of Ilton. I reiterate my support given in Grand Committee for the appointment of a patient safety commissioner, and I thank both the Minister and the noble Baroness, Lady Cumberlege, for the work they have done together to get to this point.

To reflect on the speed since the report of the noble Baroness, Lady Cumberlege, I remind noble Lords of the report, in the early 1970s, called *Sans Everything*, about the terrible atrocities and lack of safety in some in-patient mental health services. It took nearly a decade for that to be taken seriously, so we warmly welcome the speed with which we are dealing with this situation now.

I am delighted that Amendment 54, which will be moved by the noble Lord, Lord Bethell, on behalf of the Government, will identify the principles relating to core duties, involvement of patients and amendment to primary legislation, together with regulations for appointment and operation of the office for the commissioner. I too have concerns about paragraph 3(3) of the proposed new Schedule A1, concerning the statement:

"A relevant person must, so far as reasonably practicable, comply with a request by the Commissioner".

This means that a reluctant organisation—we need to remember that some very small organisations deliver healthcare on behalf of the NHS—or individual is potentially provided with an excuse not to co-operate with the commissioner on a reasonable request. I ask the Minister: could the words

"so far as reasonably practicable"

be removed?

Clarity over roles and responsibilities will be key to maximising patient safety, as will the independence of such a commissioner. It may well be that, as we work forward, we can be clear about the level of independence to ensure that, as they revise the principles of better patient safety, they consider not only patients in hospitals and mainstream community care but patients further afield, particularly in areas provided by the independent and charitable sector.

3 pm

As other noble Lords have acknowledged, it will be necessary in any development of the commissioner for patient safety's office to clarify roles and accountability in relation to the MHRA, and to negotiate the most appropriate approach across the four nations of the UK in relation to the commissioner.

Finally, in several briefings received on this matter it has been stressed that it will be important to ensure that the office of the commissioner, and any other associated committees or boards, reflects the diversity of our population and a range of patient experiences involving mental health and learning difficulties, as well as the physical health problems so sadly outlined in the report by the noble Baroness, Lady Cumberlege. I hope that we will also ensure that we embrace all chronological ages of our society that are served by our healthcare services. Can the Minister inform us whether these important issues of representation will be carefully considered?

Lord Mackay of Clashfern (Con) [V]: My Lords, I would like to join in the praise that has been very well entitled from the many people who have spoken today, and at other times, in thanking the noble Baroness, Lady Cumberlege, and her team for the excellent report, which lies at the beginning of this development. I thank my noble friend Lord Bethell and his team for the way they have taken this forward, because I am conscious—I have tried to think about it quite a bit—of how difficult this has been. I feel that, apart from some questions that have been raised—which I do not seek to mention again as it would be useless repetition—the scheme that is involved in these amendments is very good indeed. I shall say one thing about it in a few minutes.

It is quite clear to me that safety in the NHS and in other services is an extremely important matter. When you see the amount of money that the Health Foundation pays out in respect of claims against the health service, it is fairly plain that it is a very serious problem, in fact, and one which has been found to be extremely difficult to reduce substantially. The money that goes out for these claims is a very substantial proportion of the total amount spent on the health service, so this is certainly a very important area, and it is important that it should be attended to in this way as soon as possible.

When I read the report originally, I felt that it revealed a very urgent and important problem in the health service, and that it was vital that patients should have a voice when damage emerged from a particular source, particularly where that source was in some general use. There can be no question but that this is a difficult problem and that it will take all the skill and command of the Government to produce a satisfactory and workable answer.

The report emphasises the need for principles to guide the commissioner and the wisdom of seeking the help of the public to enunciate them. I am very pleased that the Government have taken this on and that the Scottish Government have also indicated their hand to tackle this problem. Although health is devolved, it is important that, if it is at all possible, the answer to this question is agreed across the whole of the United Kingdom.

The title of the report is *First Do No Harm.* However, the report indicates harm having been done in a number of cases. Many treatments start with an incision and, sadly, some patients pass away on the operating table. In none of these cases do any of the practitioners involved intend to do harm. Surely this shows the calibre of the person required to take on this essential role. To enunciate the principles involved in patient care I consider to be an extremely important labour and a task demanding a person of tremendous responsibility.

I strongly support these amendments, subject to the questions that have been raised, and I am happy that they have been put forward so fully at this stage by the Government.

Baroness Jolly (LD) [V]: My Lords, the amendments in this group relate to the introduction of a commissioner for patient safety. We have supported this proposal right from the publication of the review, *First Do No Harm*.

At Second Reading and in Committee we supported the amendments tabled by the noble Baroness, Lady Cumberlege, to put the patient safety commissioner on a statutory basis, as recommended in the report of the Independent Medicines and Medical Devices Safety Review. I was pleased to add my name to Amendment 65, tabled by the noble Baroness, Lady Cumberlege, that we are debating. Along with all the government amendments, it will enable the progress of the commissioner's appointment. I join others in congratulating the noble Baroness, Lady Cumberlege, and the Minister, the noble Lord, Lord Bethell, for getting the patient safety commissioner accepted so quickly by the establishment.

The critical issue is to be independent, and to be seen to be independent by example. As the noble Baroness, Lady Finlay, mentioned, both the children's and the victims' commissioner have remained independent, and I am sure would be useful allies and candid friends in the world of commissioners—who, as the noble Baroness, Lady Cumberlege, underlined, are not regulators.

I look forward to the time when in every NHS healthcare setting there will be easily accessible information on the role of the patient safety commissioner, and the way to contact them. We welcome the department's commitment to working at pace, and there are many parliamentarians here today who will be keen to ensure that it does just that.

As the noble Baroness, Lady Cumberlege, said, there is a time pressure to appoint the commissioner. I join the noble Lord, Lord O'Shaughnessy, the noble Baroness, Lady Bennett, and others, in their concern for the pace of the appointment. What body will have oversight of setting up the office of the patient commissioner? I wonder whether the Minister could tell the House when he would expect the office to be up and running—in a year, in two, or more?

Baroness Thornton (Lab): My Lords, I can only join in with the congratulations that everybody has expressed in this debate today. I congratulate of course the noble Baroness, Lady Cumberlege, and support her—as we have from these Benches throughout. I also congratulate and thank the Minister, the noble Baroness, Lady Penn, and also somebody who I do not think has been mentioned but I do remember sitting giving his wisdom in the many discussions we have had, who is of course the noble Earl, Lord Howe. I think the team were very wise indeed to have him sitting with them.

I am not going to say very much because I think we are there with this. Most of the questions that needed to be asked have been asked: on speed, independence, resourcing and powers, and on the issue of "relevant person", which several noble Lords mentioned. These are the key issues.

One issue that has not been mentioned—here I thank the PSA for its brief—is the need to ensure that there is no reduction in public protection in any other areas of government policy, and that the remit of the role should link closely with the work of the other bodies involved in patient safety.

Finally, I have to say that I agree with the noble and learned Lord, Lord Mackay of Clashfern, that there has to be a four-country element in this. As the role is intended to cover only England, there should be consideration of how the link with equivalent or complementary mechanisms will work in the other countries of the UK. Otherwise, we might find ourselves with a dissonance here, which will not be in patients' interests.

Lord Bethell (Con): My Lords, I will save my Hollywood thank-yous for the end of the process, but profound thanks will need to be said. I want to say specific thanks to those who have spoken in the debate on these amendments. There have been a large number of very thoughtful comments. The noble Baroness, Lady Thornton, and my noble and learned friend Lord Mackay both mentioned four nations and devolution. The noble Baroness, Lady Bennett, spoke on gender, my noble friend Lord O'Shaughnessy on industry advocacy, and the noble Baroness, Lady Ritchie, on Northern Ireland. It is a very long list, and I cannot address every contribution. What I will do instead is address what I think have been the key points in the debate on these very important amendments.

Amendment 65 was tabled by my noble friend Lady Cumberlege before the Government's own. I am extremely grateful to her and her team, who have written to me expressing their thoughts. The government amendment would not have been possible without her continued engagement and that of other noble Lords whose experience and knowledge have been essential in shaping the Government's thinking. Although there are differences between our amendments, we are agreed on the fundamental point that we must create a patient safety commissioner in order to give the voice of patients its rightful prominence. My noble friend Lord O'Shaughnessy has made that point extremely clearly and effectively.

More broadly, I hope that the amendment in my name assures my noble friend Lady Cumberlege and the House of the seriousness with which the Government takes the report *First Do No Harm*. The Government will continue to review this report. We made a Written Ministerial Statement on the report and its recommendations yesterday, and will respond to the whole report shortly.

A patient safety commissioner, as proposed in Amendment 65, would promote the interests of patients and other members of the public in relation to the safety of medicines and medical devices. The Government entirely agree that listening to patients is essential to preventing the sorts of issues highlighted in the report. On this, our visions for the patient safety commissioner are as one.

However, Amendment 65 in the name of my noble friend Lady Cumberlege differs in specific ways. Her proposed new subsection (2) provides that the Cabinet Office would host and fund the patient safety commissioner. My noble friend has argued here and in Committee—and, indeed, in her report—that this would be necessary to safeguard the independence of the commissioner. I simply do not agree. It is common practice for commissioners to be sponsored by the government department with relevant policy responsibility, and it is entirely unclear to me what the benefit of sponsorship elsewhere would be. The process of public appointments is set out clearly; there is no question of

[Lord Bethell]
undue influence by the sponsoring Secretary of State. The process is there—in fact, it is public. Nor does the identity of the sponsoring department amend or change the powers and functions of the commissioner; it is simply how the body is supported.

There are also differences in the way in which my noble friend's intention is executed. In her report, she was clear that working with other bodies was necessary and, as I would hope, obvious as part of any commissioner's remit. However, Amendment 65 is unclear as to how the commissioner would interact with other regulatory bodies. For example, proposed new subsection (5)(e) would allow the commissioner to receive direct reports from patients and any other persons, including regulators and the public. However, the CQC, the Parliamentary and Health Service Ombudsman and the MHRA, among others, are all open to receiving direct reports from patients and the public. They have a responsibility to listen to complainants. These bodies also have their own routes for reporting. For example, as we know from the vaccines rollout, adverse incidents relating to medicines and medical devices are reported through the MHRA's yellow card scheme.

Without differentiation between taking receipt of direct reports to further a broader investigation and acting as an ombudsman, Amendment 65 might create a body overwhelmed by patient reporting and investigating individual cases. The noble Lords, Lord Patel and Lord Hunt, both referred to past agencies here, but where the best route to resolution sits elsewhere. The report itself said that the commissioner should not investigate individual cases, yet this boundary is absent from the amendment.

Proposed new subsection (7) enables the commissioner to require information from public bodies and others for the purposes of producing and laying before Parliament reports regarding patient safety, but "other" would extend to private individuals—a very expansive group indeed. The amendment tabled by my noble friend provides for the commissioner to make reports only to the Secretary of State and Parliament, and not to a range of bodies as in the government amendment. Nor does my noble friend's amendment provide for what would happen if these individuals did not respond.

"Relevant person" is a broad definition. I am confident that it will enable the commissioner to engage with the organisations necessary to fulfil their functions effectively. In addition, proposed new paragraph 3(1)(b) of Schedule A1 would enable the commissioner to receive information from and consult

"any other person the Commissioner thinks appropriate".

This provides the commissioner with all the relevant tools necessary. A vital difference between my amendment and the proposals of my noble friend is that, in mine, provisions are made for the patient safety commissioner to make reports and recommendations to relevant public authorities or persons, and for that authority or person to have a duty to respond to these; I think that is vital.

3.15 pm

We have listened, and made substantial changes in this area since Second Reading, so I signal to my noble friend that I do not anticipate debating any amendments at Third Reading.

My noble friend has raised the issue as to whether the words "reasonably practicable" are a fetter on the commissioner, saying that they might prevent the commissioner obtaining information. To this I would say that the language used in our amendment is exactly—or almost exactly—as it is for the Children's Commissioner and the Domestic Abuse Commissioner. They are no different. "So far as reasonably practicable" provides for circumstances where a body is asked for information it simply does not hold, or, say, information is requested to be sent via email when the information held cannot be transferred from one IT system to another. Without the words "so far as reasonably practicable" there is no means to be compliant. It is fair to have that language in there. Such language reflects that the commissioner may ask for the impossible or the undeliverable, but it is not a shut door. We would expect that a refusal on the basis that it is not reasonably practicable to comply would open up a dialogue on what was practicable.

However, the commissioner is armed with tools for additional action if met with non-compliance. The commissioner could, for example, bring that non-compliance to the attention of the body's regulator, the Secretary of State or Parliament. In a system that can sometimes seem crowded, it is essential that each organisation is able to work in a way that is complementary, so that the system becomes greater than the sum of its parts.

I hope my noble friend can acknowledge that we differ here on very few matters. We discussed this in Committee and had conversations after that. The Government's position on this has not changed and our view will not change between now and Third Reading. I therefore hope that my noble friend will not feel that she has to push her amendment. If she wishes to test the opinion of the House, she should do so now.

The Deputy Speaker (Lord McNicol of West Kilbride) (Lab): I have received one request to ask a short question. I call the noble Baroness, Lady Cumberlege, to ask a short question for elucidation.

Baroness Cumberlege (Con) [V]: My Lords, I want to say one or two things very quickly. I thank those who have spoken; it has meant such a lot to me. The noble Baroness, Lady Jolly, and the noble Lords, Lord Patel and Lord Hunt, have been there since the very beginning of this journey.

I say to the Minister, as I should have said at the very beginning, that I will withdraw my amendment. I have no wish to take it further. I do think that the Cabinet Office would have provided us with more independence, but my noble friend the Minister said at the very beginning that this was a red line and it was no good my pursuing it. I took that hint and I have not argued it anywhere. Hearing the Minister talk about independence today—getting it on the record—has been really important. However, as the noble Lord, Lord Lansley, said, of course influence matters as well, and I take that.

I will say a very quick word about the timetable, which is critical. In our recommendations we wanted to set up a task force to implement this under the aegis of the Department of Health and Social Care. That

has been rejected by Ministers. That is a tremendous pity. Noble Peers are concerned about the timetable; so am I.

It has been said that this has been very quick. No, it has not. Those of us who have run companies know what "quick" means: if your company is to survive you have to act very quickly. This is not quick. I will put pressure on through other means, particularly the all-party group, to get this implemented as soon as possible, because people are suffering. People are in dire straits and we have to stop this awful damage that is being done to lives. The quicker we can do this, the better. I am sure my noble friend will agree with that.

I know when I am beaten, but I also know what needs to be done. I do not want to go through the point of view of the Cabinet Office, but it is absolutely critical that this appointment is made speedily, because people are suffering and we should avoid that if at all possible. I believe that the patient safety commissioner will grasp this issue and ensure safety, which, as my noble friend the Minister said, has run through the Bill. I thank him for that, but it will not happen until this appointment is made. I am afraid that I will press very strongly on that.

I thank all noble Lords for taking part. I wish I could go through this in detail, but it is not my remit to do so. I thank noble Lords so much for their support.

Lord Bethell (Con): I thank my noble friend for her very kind and generous words, and for making it clear that she will not move her amendment. I reassure all noble Lords that their words are on record and will have a bearing and influence on the development of the patient safety commissioner as it is rolled out.

My noble friend's question was about timing and speed. I hear her admonishments loud and clear. She knows that once we have committed to something we will deliver it. I ask for her forbearance. There is a global pandemic on. I cannot guarantee that this is the number one priority because we need to do the vaccine and we have to get Britain back on its feet. Those are distractions that I cannot hide from the House, but I reassure my noble friend and all those involved in the debate that a commitment has been made very clearly and we are now moving to deliver it.

Amendment 1 agreed.

The Deputy Speaker (Lord McNicol of West Kilbride) (Lab): We now come to the group beginning with Amendment 2. 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 the debate.

Clause 1: Power to make regulations about human medicines

Amendment 2

Moved by ***Baroness Thornton***

2: Clause 1, page 1, line 8, 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 1 of the Bill requiring the Government to return with primary legislation. It is linked to the sunset amendments for Parts 2 and 3 of the Bill, and the amendments in the name of Lord Patel requiring consolidated legislation.

Baroness Thornton (Lab): My Lords, in moving Amendment 2 I will speak also to Amendments 27 and 40 in my name. I also support the amendments in the names of the noble Lords, Lord Patel and Lord Kakkar, and of the noble and learned Lord, Lord Mackay.

This amendment would provide a sunset provision for Part 1, requiring the Government to return with primary legislation. It is linked to the sunset amendments for Parts 2 and 3 and the amendments in the name of the Lord, Lord Patel, requiring consolidated legislation. We discussed all these issues in Committee. Through discussion, the noble Lord, Lord Patel, the noble Baroness, Lady Jolly, and others have joined together to put this together as a suite of amendments, which makes sense.

At Second Reading, the noble Lord, Lord Blencathra, said:

"Thus it grieves me to say that the structure of the Bill is absolutely atrocious and an affront to parliamentary democracy. Of course, it is not unique; it is just one more Bill stuffed full of Henry VIII clauses but devoid of substantive content. It is the barest skeleton, all to be filled in with negative secondary legislation.

I am speaking in my capacity as chair of the Delegated Powers Committee. We considered the key clauses—Clauses 1, 8 and 12—and concluded that they contain inappropriate delegations of power. We say that

'the Government have failed to provide sufficient justification for … the Bill adopting a "skeleton bill" approach, with Ministers given very wide powers to almost completely re-write … regulatory regimes'."—[*Official Report*, 2/9/20; col. 415.]

Here we are some distance away from that remark. Indeed, the question we must ask is: have we succeeded? Is the Bill less atrocious now than at the beginning when the DPC was so scathing?

All of us, in particular the Minister, the noble Baroness, Lady Penn, and the Bill team, have listened and improved the Bill. The Government have worked hard to meet some if not all of the Constitution Committee's and the Delegated Powers Committee's recommendations.

We believe that this suite of amendments, in a way, builds on those improvements that have already been made to the Bill. They propose a very simple objective that was articulated from the very beginning. It is neither democratic nor safe to run medicines, devices and veterinary medicines through regulation alone in the long run. Our regulatory framework needs to be in primary legislation. This must be achieved in a timely fashion, hence these amendments. Sooner or later—and there is agreement on this—there will need to be consolidation in primary legislation. We would prefer it to be sooner. We think that some agreement is necessary on this.

While I recognise the need to get this legislation on the statute book, the Minister must know about the disquiet that some of this has caused and the need to address the issues of accountability in regulation. The truth is that while we are very pleased to now have affirmative regulation, it is very rare for that to be

[Baroness Thornton]
rejected once it reaches Parliament, however unsatisfactory it might be. In fact, we have learned a great deal about regulation over this year of Covid regs.

The amendments in my name and those of the noble Lord, Lord Patel, and the noble Baroness, Lady Jolly, would amend Parts 1, 9 and 14, which concern the three objectives of the regulation of medicine, medical devices and veterinary devices, with a three-year sunset provision. In Committee, I proposed that there should be consolidation of regulatory legislation within a two-year period, so I hope the Minister might recognise that we have been quite generous here because we have now extended that to three years.

Other noble Lords who are much better qualified than I will discuss the merits of the group. I look forward to hearing their discussion. In the meantime, I beg to move.

Lord Patel (CB) [V]: My Lords, I support the amendments in the name of the noble Baroness, Lady Thornton. As she said, they should be read in conjunction with my Amendments 26, 39 and 63 on the need for consolidating legislation, which I will come to in a minute.

As has previously been debated, the Bill confers an extensive range of delegated powers relating to medicines, veterinary medicines and medical devices. Previously, the power to create relevant secondary legislation in the UK was derived from the European Communities Act 1972. Those delegated powers were simply to allow the implementation of laws in the UK that have already been consulted on, debated and scrutinised at EU level and by our own EU committees in the Lords.

The powers in the Bill are such that areas of policy that previously would have been subject to greater scrutiny at EU level may now be amended without similar levels of scrutiny in the United Kingdom. They do not, as such, represent an equivalent conferral of power to the legislature seen under the previous regulatory arrangements.

3.30 pm

As has been mentioned, the House of Lords Constitution Committee recommended that, although delegated powers are appropriate to make provision for minor and technical matters, it is essential that primary legislation is used to legislate for policy and other major objectives. The risk of delegated powers that provide significant flexibility is that substantial policies are amended, and not merely implemented, by secondary legislation. That was also emphasised in the report of the Delegated Powers and Regulatory Reform Committee, which concluded that the Bill represents an unjustified delegation of power. I admit that the Government state that the Bill is intended to be primary legislation and they have brought in amendments to improve it, but, although amendments in Committee increased the scrutiny that these powers will be subject to, they still cover wide areas of policy that should properly be the subject of primary legislation.

As the Bill stands, the delegated powers conferred would allow the Government to make substantial policy changes in these areas through secondary legislation as a matter of course into the indefinite future. These powers conferred by the Bill go far beyond what is either necessary or prudent, and for that reason there should be a time limit on them. Therefore, I support this amendment.

Before speaking to my own amendments, I thank the noble and learned Lord, Lord Mackay of Clashfern, the noble Baronesses, Lady Thornton and Lady Jolly, and the noble Lord, Lord Kakkar, for putting their names to them. My amendments would require draft consolidated legislation for human medicines, veterinary medicines and medical devices. Together, the new clauses that I propose and the other, related amendments would require the Secretary of State to publish draft consolidated legislation within three years. I realise that that is a tall order, and there might be some discussion about the period required to streamline the existing regulatory framework.

As I said, these amendments are linked to the one moved by the noble Baroness, Lady Thornton, providing for the three-year sunset provision. They would create an obligation to draft primary consolidating legislation in respect of human medicines, veterinary medicines and medical devices and are intended to be read together. The need for clauses requiring consolidated legislation is inextricably tied to the time-limiting of powers conferred by the Bill, as primary legislation will still be needed to form the basis of the regulatory regimes in these areas.

Of equal concern is that the existing regulatory regimes for medicines and medical devices are complex and unwieldy, spanning multiple pieces of primary and secondary legislation that implement several EU directives. This existing complexity has only been added to by several more pieces of secondary legislation in these areas, implemented in preparation for Brexit.

In Committee, I tabulated at length—it ran to a couple of pages—the different regulations that have been brought in, since the early days, because of the directives and regulations. For example, currently the regulatory regime for medical devices consists of the Medical Devices Regulations 2002, which implemented three different EU directives, and the Medical Devices (Amendment etc.) (Exit) Regulations 2019. The 2019 regulations were intended to ensure that the existing Medical Devices Regulations continued to operate correctly once we left the EU, but then other regulations were added to it. Those are examples of how many different regulations there are and, therefore, of the need for consolidation.

In addition to those uncertainties, in the final months of 2020 several new statutory instruments were laid before Parliament setting out complex new systems of regulation for medicines and medical devices as between Northern Ireland and the rest of the UK. The situation with Northern Ireland greatly adds to the complexity of regulation and has implications that we are only just beginning to understand. This matter should be of prime consideration. Once the shape of relations with the EU becomes more apparent, clarifying this complex relationship will become a priority for stakeholders and patients alike.

As it stands, the Bill merely grants powers to create future regulations through statutory instruments, simply adding to the existing regulatory complexity.

Not consolidating or clarifying any of these issues could lead to further uncertainty among stakeholders about their obligations. This demonstrates the need both to time-limit these delegated powers and to ensure that consolidating primary legislation is introduced to Parliament after three years—although, as I said, I recognise that it might take longer—in order to subject any policy changes to adequate scrutiny.

The lack of detail in the Bill and the broad delegation of powers, with no indication of the substantial content of future regulations created by them, provide no clear or certain path ahead for regulations covering medicines and medical devices to be either scrutinised or relied on by stakeholders. For those reasons, these amendments and those linked to the amendment moved by the noble Baroness, Lady Thornton, will limit the extent of these broad delegated powers and require the Government to return with consolidated legislation in respect of human medicines.

The Deputy Speaker (Lord McNicol of West Kilbride) (Lab): After the next speaker, the noble and learned Lord, Lord Mackay of Clashfern, I will call the noble Lord, Lord Kakkar.

Lord Mackay of Clashfern (Con) [V]: My Lords, I strongly support the amendments dealing with consolidation. I regard it as very important that the legislation that controls medicines, medical devices and veterinary medicines is consolidated in a way that makes it possible for an interested person easily to achieve knowledge of the regulations. After all, when you think of how important medicine is—we have just had a considerable debate about its safety—it is important to make sure that those who administer and operate the system know the rules. If you do not know what the rules are, the chances are that you will be misled into thinking that you know when you do not know at all. Therefore, it is important to make sure that we do everything we can to lay before those who practise these arts the true rule that has been set down, and it should be possible for them to reach it without too much research into a number of statutory instruments.

We just need to think for a moment about the current virus regulations. I have had occasion to look at them from time to time, and it is quite difficult to follow what is required at a particular moment in England, Scotland or other parts of the United Kingdom. If that is the position in relation to the virus, it is obvious that the general position in relation to these sciences as a whole will be even more difficult. Therefore, I regard it as vital—indeed, as a fundamental duty of government—to ensure that the regulations on these important matters are clear and the rules accessible.

I am not very keen on the sunset clause because, if it operated without consolidation, we would be in a pretty difficult position. Therefore, I regard it as vital to require consolidation.

I am aware of the difficulty of consolidation. For a short time, I was the chairman of the committee on consolidation and, when it sat, it was extremely difficult to get a quorum because people did not find the exercise interesting. But unfortunately, although it might not be very interesting or novel, in the sense that you are not doing anything very new, it is absolutely vital to allow the system to work properly. So I regard it as important that that is put into the statute as an obligation. If we are allowing the Government to legislate in these important areas by statutory instrument —the criticism has been levelled that they are doing so too much—that should be replaced in a reasonable time. Three years is probably quite reasonable, but I am very willing to hear whatever is said about that. I regard it as very important that this is an obligation on the Government as a condition of getting away with this method of legislating quickly in this area.

Lord Kakkar (CB) [V]: My Lords, it is a pleasure to speak in support of Amendments 29, 36 and 63 in the name of my noble friend Lord Patel, to which I have added my name, and broadly for the principles of the other amendments in this group. This is a critical area of public policy, as we have heard in this debate and in the excellent debates on these questions in Grand Committee. We have also heard that the regulations—the legislation attending medicines, medical devices and veterinary medicines, and their regulation in our country —have appeared on the statute book as a result of facilitations through the European Communities Act 1972. These represent in many ways a haphazard patchwork of regulation, created over time, with good intention, but obviously with the need to be consolidated and brought to a clear and precise place, as we heard from the noble and learned Lord, Lord Mackay of Clashfern, in such a way that any party interested in this vital area, which impacts on the lives of every citizen, can do so with simplicity, understanding obligations, understanding their rights and protections and being able to act confidently with regard to the rule of law.

The current regulations represent a challenge, and as a result of our departure from the European Union, there remains much contemporary regulation, agreed at the European level, with specific reference to clinical trials and medical devices, that has yet to be incorporated into domestic legislation, once again representing an important challenge with regard to the framework within which we are to proceed.

The Government rightly have stated that patient safety is at the forefront of their thinking when it comes to regulations regarding medicines and medical devices. To bring clarity will improve safety and will also achieve the Government's other stated objective of ensuring that our country can continue to lead globally in the life sciences. We have seen the benefits of that leadership during the Covid pandemic, in terms of innovation, the application at scale and pace of that innovation for the benefit of our citizens, and the sharing of that knowledge globally.

Therefore, it is difficult to understand why Her Majesty's Government would reject the opportunity to commit to consolidating legislation so that simplified, clear, effective and intuitive regulatory regimes exist in our country and can deliver the objectives that we all agree upon. In Grand Committee, we heard from the noble Lord, Lord Lansley, an interesting proposition that the Law Commission might be approached to support the task of consolidating legislation in this area of public policy. We have heard from the noble and learned Lord, Lord Mackay of Clashfern, that

[Lord Kakkar]
when he chaired a committee of consolidation there was little interest in dealing with some of the more demanding and exacting elements with the fastidious nature that is required to create effective consolidated primary legislation. Has the Minister had an opportunity to explore whether the Law Commission might be approached on the basis of the Law Commissions Act 1965, to determine whether it would be in a position to propose and engage with the consolidation of legislation regarding medicines, medical devices and veterinary medicines, as part of its forthcoming 14th programme under the obligations and opportunities afforded by the Law Commissions Act?

3.45 pm

A failure to do this would be a lost opportunity. There is strong support for this Bill and a recognition that it must be passed in its current fashion as rapidly as possible. However, there is also a strong recognition that many of the issues are tied up in long-standing regulation created over a period of time, without the clarity and benefit of understanding the opportunities and risks offered by modern medical practice and innovation in healthcare. Not to consolidate would put our country behind rather than at the forefront of the opportunities that are afforded by being leaders in this area.

Baroness Masham of Ilton (CB) [V]: My Lords, I support these amendments. It seems totally sensible to consolidate legislation so that it is not fragmented and some medicines do not get missed. Medicines and medical devices are vital to some people. We depend on many of our medicines and devices coming from abroad, so bringing legislation together for human and animal medicines will help prevent mistakes. We are an island and crossing the borders has already caused problems with filling in the forms. With much-needed medicines there should not be a risk of not receiving them.

Lord Lansley (Con) [V]: My Lords, I am very pleased to follow the noble Baroness, Lady Masham, who rightly emphasises the importance of accessible and understandable legislation in this area. There are two issues. As my noble and learned friend Lord Mackay of Clashfern said, there is the question of the sunset clause and the question of the preparation of consolidated legislation.

On Amendment 2 and a sunset clause, I believe that we should reserve the imposition of sunset clauses for legislation where we anticipate that those powers may not be needed in future. This is not the case with this legislation. With the end of the transition period we require our own domestic legislation for medicines, veterinary medicines and medical devices, so these regulations and these powers will be required.

The points made by the noble Baroness, Lady Thornton, quite legitimately, about the framework—the rather skeletal nature of the Bill as introduced to this House—must be dealt with in other ways, and in the group led by Amendment 4, we have substantive changes which make it a framework rather than simply a skeleton, and give us greater assurance about how the powers are structured in the Bill. I hope that if she reflects on it the noble Baroness will realise that shutting down these powers three years after Royal Assent would be a very taxing imposition. It would probably mean that in less than a year and a half, Ministers would be thinking about the reintroduction of legislation. We would risk the powers in this Bill being shut down in order for a Bill very like it to be introduced in a couple of years' time. I see no intrinsic purpose in that, so I cannot support Amendment 2.

I do however want to specifically refer to the other issue of consolidation and Amendments 26, 39 and 63, in the name of the noble Lord, Lord Patel. There is a general proposition that people agree that, notwithstanding that additional regulations are going to have to be made in the weeks and months ahead using these powers, they will continue for the time being to be a complex mix of powers. Some will use this legislation, some will be in retained EU law and some will be in existing and other statutes and regulations.

What we want, as my noble and learned friend Lord Mackay of Clashfern quite rightly emphasised, is legislation in this important area that is understandable and accessible. These are not regulations for the benefit of lawyers; they are regulations for the benefit of practitioners, so they need to be very clear. The noble Lord, Lord Kakkar, helpfully and kindly referred to the points I made in Committee about the role of the Law Commission. As I understand it, indeed, I think it is well to remember two things about this. First, Law Commission members are the experts in the process of codification and simplification. Consolidation of legislation is valuable, but it is even better for it to be codified and simplified so that the end result is far more accessible and understandable to practitioners.

So I would very much recommend that we proceed by asking the Government to put the areas of human medicines and medical device regulation, and perhaps veterinary medicine as well, into the work programme of the Law Commission. As I understand it, the 14th programme of work for the Law Commission will be the subject of discussion between the Government and the Law Commission up to the spring of 2022. The work programme of course will happen subsequently. So I do not think any rigid timetable should be imposed. I hope that the noble Lord, Lord Patel, would not insist upon a three-year limit or his amendment for this purpose because I hope that, at the end of this process with the Law Commission, we will end up with something much better that is brought forward as a Law Commission Bill—which can have an expedited process of scrutiny and passage through both Houses. As a former Leader of the House of Commons, and therefore responsible for the Government's legislative programme, I say that all the evidence tells me that, if a requirement to insert a Bill into the Government's legislative programme can be avoided, it should be.

We have been there with a Law Commission Bill on the regulation of clinical professions and professions allied to medicine, which is still waiting for legislation, because it included not only codification and simplification but substantive changes to the policy—so I am afraid that it is still waiting. So let us not go down that route; let us do the very sensible thing rightly initiated by the

noble Lord, Lord Patel, which is call for consolidation, making sure that it is not about changing policy but about making the legislation work effectively for the benefit of the various practitioners and those who depend on them. And let us work through the Law Commission. I hope that, if the Minister were to tell the House that he and the Government were willing to proceed in that direction, without a timetable in place, the noble Lord, Lord Patel, would not press his amendment when the time comes.

Lord Hunt of Kings Heath (Lab) [V]: My Lords, rather like the noble Lord, Lord Lansley, I see this as a group of amendments in two parts. The argument for consolidated legislation from the noble Lord, Lord Patel, was very ably supported by the noble and learned Lord, Lord Mackay, and I very much support it. For those working in the health service or in industry, trying to wrestle with all the elements of legislation that cover health is very difficult indeed, and the case for consolidating legislation every so often is a very powerful one. I very much hope that the Government will take note of this, bearing in mind of course that there have been strong arguments from NHS England for a further NHS reorganisation Bill, which might be coming within a short space of time. On that issue in particular, the reorganisation of the NHS, the need to consolidate legislation following such a Bill becomes very persuasive indeed.

Where I do not really agree with the noble Lord, Lord Lansley, is on his remarks on Amendment 2 and his suggestion of a sunset clause. He argued that the problem with that is that you shut down the powers and therefore the Government need to produce another Bill, because we obviously need a regulatory regime. Sticking to the three years in my noble friend's amendment would mean that work would have to start within 18 months. That does not argue against the principle of a sunset clause, although there can be debate about the length of time in which the new Bill needs to be enacted.

The fact is that this Bill conveys a huge number of delegated powers to Ministers. In a pungent analysis, the University of Birmingham points out that, while delegated powers may be needed to ensure responsiveness to the EU transition period and to meet the challenges of technology change, they should not be used indefinitely or relied on to implement matters of policy. This is the problem. If we take this Bill and we do not have some changes in the future, Ministers ever after will be able to ram changes to medicines and medical devices regulation through the House, and the amount of scrutiny in relation to secondary legislation is limited.

The Delegated Powers and Regulatory Reform Committee was very clear in criticising Ministers for failing to provide a sufficient justification for parts of the Bill adopting a skeletal approach. The recent report from the House of Lords Constitution Committee also said that it recognises

"that the existing powers to amend these complex regulatory regimes will cease to have effect on 31 December 2020 and that alternative arrangements are required. If the Government is unable to specify the principles according to which it intends to amend and supplement the existing law, the delegated powers in the Bill should be subject to sunset clauses."

That surely must be right.

At Second Reading the Minister suggested that sunset clauses would emasculate the Bill, and in Committee he said that a sunset clause

"will not change the very good reasons why delegated powers are necessary."—[*Official Report,* 19/10/12; col. GC 327.]

I think we come then to the fundamental argument: that many noble Lords disagree with the extent of delegation that is going to be given to Ministers for all time. The only proper defence against that is to agree to the kind of amendment my noble friend has proposed in relation to a sunset clause. For that reason, I very strongly support her.

Lord Naseby (Con) [V]: My Lords, in the past I have had the privilege of working with two pharmaceutical companies, a US pharmaceutical company Upjohn and Reckitt pharmaceuticals. I think that as a country we face a unique opportunity at this point caused by Brexit and a situation where we have a major industry which has all the potential to be a world leader. But this point in time is going to go away unless we act. This is a watershed Bill. It creates an opportunity to enhance the role of the UK Medicines and Healthcare products Regulatory Agency. The industry and all of us should want the UK to be an attractive market for investment in medicines, medical devices and therapies for all our UK patients. It creates an opportunity to make significant improvements in UK clinical research environments and, very importantly, it increases the commercial trial activity to make the UK the number one destination for life sciences supporting UK public health.

4 pm

This is a real opportunity but, as other noble Lords have said, there is a mish-mash of no end of Bills that need to be consolidated. I support what the noble Lord, Lord Patel, said. Having worked with two of these major pharmaceutical companies and sat down with their lawyers, as I have in the past, particularly in the days of PPRS, if you are in industry you realise that there is so much legislation to be so careful about. Consolidation therefore should be taken very seriously.

Sitting here this afternoon, I do not actually know what the right procedure should be. However, having been in the other place, I am very wary of Law Commission Bills. They do not have a history of working quickly and still do not necessarily result in something positive happening on the ground in the context in which they are working. I urge my noble friend on the Front Bench to sit down with, among others, the ABPI and the other leading authorities involved in this industry to talk about how we can get consolidation put together. That way, anybody thinking of investing in the life sciences in the UK will realise that we have a well-organised ship. They will know that they can choose the area where their own expertise is, and exactly what the situation is there.

As for sunset clauses, I have never been in favour of them in what I would call the creative part of industry. It seems that they usually do not work because the nature of this industry is that some developments take years and years to come to fruition. The market changes. Gosh, we have just had a prime case history in Covid-19,

[LORD NASEBY]
to which the world has responded—and, in particular, our people have responded. But even now, we do not know the answer to all the different phases of it. So I hope my noble friend on the Front Bench will recognise, as I am sure he does, that we have an absolute watershed Bill here, creating a huge opportunity for our country. However, personally I would not put a sunset clause in. I would like to see some work done, particularly to have consultations with industry on which consolidated legislation would really work.

Baroness Jolly (LD) [V]: As the noble Lord, Lord Hunt of Kings Heath, and others have said, these amendments relate to sunset provisions and consolidated legislation. As we have already heard, the Bill is largely a skeleton Bill and allows the Secretary of State or a relevant authority to make legislation by statutory instrument on policy issues relating to human medicines, veterinary medicines and medical devices. Can the Minister confirm whether the SIs referred to will come before the House? Will he also confirm that the SIs we see will live up to the expectations of the noble Lord, Lord Blencathra, and his committee?

It is important that there is a limit on how long the delegated powers should last. The amendments in the name of the noble Baroness, Lady Thornton, would mean that, after the suggested three years have elapsed, the policy objectives of the Government would be clearer and they could return with primary legislation. The amendments in the name of the noble Lord, Lord Patel, would require the Government to publish the consolidated primary legislation in draft form. We support these measures but, for the intervening period, we believe that the powers should be subject to the additional scrutiny required by my noble friend Lord Sharkey's amendments in the next group.

Lord Bethell (Con): My Lords, I thank noble Lords for an extremely powerful session on these amendments. I confess that I completely share the aspiration voiced by many noble Lords about Britain having the best possible legislation on life sciences in the world. As the Life Sciences Minister, that is a natural ambition, but it is also a real possibility, and it is what we are working towards at the department, and through the Bill. But I have severe reservations about whether this approach is the right mechanism, and I would like to address those directly.

The noble Baroness, Lady Thornton, has tabled Amendment 2, which relates to the sunset clause, and with this amendment it would be convenient to speak to Amendments 26, 27, 39, 40 and 63. I will come to Amendment 2 shortly but, first, I cannot say that Amendment 26 is a big surprise. The noble Lord, Lord Patel, who authored it, indicated as much when he and other noble Lords discussed these matters after the excellent debate in Grand Committee. The intent of his amendment is to require the Government to publish draft legislation within three years—legislation that consolidates medicines and medical devices regulation. I understand the arguments made during Committee, and again here today, that the regulation could benefit from clarification and those arguments made on how secondary legislation could be used. The amendments in the name of the noble Baroness, Lady Thornton, go further. They would append a sunset clause after three years—I repeat, three years—requiring not draft legislation but passed legislation.

I start by addressing the timing put forward. The noble Lord, Lord Patel, asks for the Government to publish draft legislation within three years of Royal Assent. I assume that he intends this consolidation effort to include changes made under the delegated powers in the Bill, including policy that may be made to, for example, take forward a national falsified medicines scheme. The noble Baroness's amendment would have the delegated powers lapse entirely, leaving us without the ability to amend or supplement the regulatory regimes at that point. In reality, three years between Royal Assent and draft legislation ready for publication that consolidates the existing legislation and includes any changes made under the Bill is just not long enough. Each change to the regulatory regimes will take time. Public consultation must be conducted and amending regulations must be laid, debated and so on. We do not intend—in fact, it would not be possible—to front-load policy changes into the first half of 2021, let alone 2021 at all.

Noble Lords have spoken to the importance of consultation. I say it would not just be the Government front-loading legislation; it would be about asking the affected sectors to engage with a lot of consultation very quickly and in parallel. That does not seem the right way to go about it at all. It inevitably means that the sorts of exciting policy changes that support our life sciences sector and protect patients will take an enormous amount of time to stand up. Developing and consulting on policy proposals that require legislative changes takes time, as does the drafting of any proposed legislation. Before getting to the point of drafting the legislation and so on, you need to have made an assessment of what it would be appropriate to consolidate —and that takes time.

The Human Medicines Regulations 2012 were the product of a consolidation exercise that required extensive consultation. Consultations were run while explanatory documents setting out changes so far, and so on, were all prepared before the regulations were made. Let me be clear on the timescale involved in that exercise. A concept paper was issued by the MHRA in 2009. There was an expectation that consolidating human medicines regulations, including looking at the Medicines Act 1968, would take around three years to complete. That concept paper was put out to consultation; a response was published and further consultation took place in 2010.

The first complete draft of the regulations was published in August 2010 and a number of specific consultations also run in that year. A further consultation, following the consultation on the draft regulations of August, was run between October 2011 and January 2012. Three years is the time it takes to do the comprehensive exercise that the noble Lord, Lord Patel, alludes to in his amendment, and that exercise did not involve making up new primary legislation in the first place: it resulted in the Human Medicines Regulations 2012. The noble Lord has extended his amendments to medical devices and veterinary medicines as well.

The noble Lord cannot mean us to start a review the day after this Act is given Royal Assent, with the intention of bringing forward proposals within three years. There would be no legislation made under the Act to assess. I cannot see an exercise of seeing what to consolidate and then preparing the drafting taking less than a year altogether. In fact, it would more likely take much longer if the consolidation is intended to be as far-reaching as the noble Lord and others have very powerfully indicated. Taken together, the noble Lord's amendments would mean that the process would need to start by 2022, but not all the legislative change to be brought forward under the Bill's powers would yet be made and in effect.

I anticipate that a consolidation exercise as proposed by the noble Lord would wish to consider the practical effects and operation of such a complex and comprehensive body of legislation. In order to do that, we would need time for the secondary legislation to be made to deliver policy. Industry then has to comply with revised regulatory changes and the MHRA needs to assess how it works. This does not, as the noble Lord may recognise, amount to a realistic exercise. We will not have all the pieces to assess before he asks us to conduct the assessment and also provide an alternative. Change takes time. The standstill period for medical devices, for example, lasts two and a half years, in recognition of this, so while some changes are likely to be made to the regulatory regimes within three years, some will not. When his proposal amounts to no more than a year of operable amending legislation to assess and consolidate—perhaps less—it is therefore impracticable.

This issue is compounded by the noble Baroness's Amendments 2, 27 and 40, which would introduce a sunset clause to the regulation-making powers in Parts 1, 2 and 3 of the Bill, in effect creating a new cliff edge at the end of three years, after which the existing regulatory regimes cannot be updated. If what the noble Baroness seeks is similar to what the noble Lord, Lord Patel, seeks—an assessment of whether secondary legislation is the right place for the regulatory regimes—I say to her that the means simply do not fit the ends. Introducing a cliff edge in legislation is unhelpful. It forces legislation on to the timescale of a sunset clause. It does not allow for pandemics or for the consideration of new developments that arise and need to be addressed.

The noble Baroness's amendments would further compress the timescale, stripping out another year. Working back from a sunset clause of three years' time, we would need Royal Assent of a new Act by then. Let us be generous and provide for a year of parliamentary scrutiny. We began this Bill in February last year; it is January now and we must allow parliamentary drafters to do their job of translating policy intent into clauses. The noble Baroness and the noble Lord have both argued in favour of a very different drafting approach: let us give them, say, a year. While that may seem a long time, I suggest that many noble Lords have experienced the challenges of drafting amendments. There are questions about intent and about the choice of language, and these would apply to tens and possibly hundreds of clauses. Suddenly, that time is not very long at all. That then leaves us with a year from Royal Assent to begin the drafting process—not even the assessment process. All the problems I have already mentioned, including the inability to set up a regime to assess and not only pass legislation but implement that legislation, apply, but much more urgently.

We must also consider the impact on those who are being regulated. The arguments I advanced in Committee on the uncertainty that this would create for businesses, manufacturers and, importantly, patients apply very gravely but would become even more critical. In effect, we would be making regulation in 2021—potentially substantive, bold new regulation to protect patients from harm and ensure the highest standards of safety for medical devices—but we would also be saying that this would be immediately under review, and potentially completely rewritten within three years. The new policy to be delivered by these regulatory changes would not be able to come into force, be implemented and enforced before we would be back here again. I simply cannot think that this is good regulation.

I am sympathetic to the issue of how Parliament assesses our plans. There are, of course, avenues open to Parliament to consider whether it wishes to express a view to the Government on any particular topic. We have Select Committees to scrutinise government policy and we have provided for a reporting requirement in the Bill that gives Parliament the opportunity to reflect on the legislation we have made under the Bill in the first two years and any plans we have at that point to make further changes in response to concerns and proposals raised in relation to it. There are institutions such as the Law Commission that can be called upon to take a view on whether legislation is the right legislation, or too complex. However, if noble Lords want me to say, "In three years, we will have made changes under this Bill that are right to consolidate, and we will be in a position then to review and assess and produce something for Parliament to look at," I simply cannot give them that assurance; nor can I say anything similar to the noble Baroness.

We need to make changes to the regulatory regimes and follow the full and thorough processes to do so, including public consultation and, most likely, draft affirmative amending regulations. We need to have them working, understood and operable by industry and the regulators. Getting that up and running is where I think we need to direct our resources, before we can think about reviews of how it works. To that end, I hope the noble Baroness understands why I am not able to concede here. I hope she feels able to withdraw her amendment and that the noble Lord will not feel compelled to press his.

Baroness Thornton (Lab): I thank the Minister for that. The words, "Yes, Minister" came to mind. It was a very long, wordy way of saying no, but I suppose he had to say it. I thank the noble Lords, Lord Patel and Lord Kakkar, the noble and learned Lord, Lord Mackay, and the noble Baroness, Lady Jolly, for their support and their speeches, as well as my noble friend Lord Hunt and other noble Lords. I particularly agreed with the noble Lord, Lord Naseby. Although we may disagree about sunset clauses, he absolutely hit the nail on the head about the need for consolidation. We link these together because we think there needs to be a time limit.

[Baroness Thornton]

The Minister said absolutely nothing about what he thinks may happen next. It is simply not acceptable, and the House of Lords scrutiny committees—the Constitution Committee and the Delegated Powers Committee—said that it is not acceptable, democratic, accountable or even safe to continue to run this area of public policy simply by regulation. Since the Minister and the Government have not brought forward anything that actually tackles that problem, that is what this suite of amendments seeks to do. All the discussion we have had in the past hour tells me that we are right to do this.

I say to the noble Lord, Lord Lansley, who mentioned the Law Commission during our discussions about this, that that is a bit of a phantom. We all know that the Law Commission works on a three- to four-year cycle. It is a law unto itself: the Government cannot instruct the Law Commission to do anything, quite rightly. That may or may not be the right way forward, but it could take 10 or 15 years: it certainly does not hurry itself. So, in theory it is quite a nice idea, but I suspect that it would probably not work within the time limits we have before us.

I listened carefully to the Minister. It was a classic explanation of why something cannot be done and, on that basis, since the Minister seems to think that nothing can be done, I beg to test the opinion of the House.

4.18 pm

Division conducted remotely on Amendment 2

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Amendment 2 agreed.

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4.32 pm

The Deputy Speaker (Baroness Garden of Frognal) (LD): My Lords, we now come to the group beginning with Amendment 3. 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 3

Moved by ***Lord Sharkey***

3: Clause 1, page 1, line 8, 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."

Lord Sharkey (LD) [V]: My Lords, the amendments in this group are in my name and the names of the noble Baroness, Lady Andrews, the noble Lord, Lord Forsyth of Drumlean, and the noble and learned Lord, Lord Judge. I am grateful for their support and regret that the noble Lord, Lord Forsyth, cannot be here today. He is currently chairing a meeting of the Economic Affairs Committee.

The purpose of the amendments is to replace the use of the affirmative SI procedure in Parts 1, 2 and 3 of the Bill with the super-affirmative procedure. This is to restore an element of meaningful parliamentary scrutiny to a Bill that so conspicuously lacks it. This is a skeleton Bill. Parts 1, 2 and 3 contain no policy detail and effectively give Ministers carte blanche to decide policy. They give the Minister almost unfettered power to remake our human medicines, our veterinary medicines and our medical devices regimes.

Our DPRR Committee and the Constitution Committee were extremely critical of this approach. On Second Reading, as the noble Baroness, Lady Thornton, has reminded us, the noble Lord, Lord Blencathra, chair of the DPRRC, and speaking for it, said that

"the structure of the Bill is absolutely atrocious and an affront to parliamentary democracy."

He went on to say:

"Parliament is effectively bypassed; that is a sick joke of good law."—[*Official Report*, 2/9/20; cols. 415-16.]

Parliament is bypassed largely because the affirmative SI procedure does not allow for real scrutiny. We cannot amend SIs, and the House has voted down affirmative SIs on just four occasions in the last 70 years.

The Constitution Committee was clear in its 2018 report, *The Legislative Process: The Delegation of Powers*, when it said:

"Without a genuine risk of defeat, and no amendment possible, Parliament is doing little more than rubber-stamping the Government's secondary legislation. This is constitutionally unacceptable."

The affirmative SI procedure does not constitute meaningful parliamentary scrutiny.

By contrast, the super-affirmative SI procedure is designed and used to deliver a measure of real scrutiny. *Erskine May*, in part 4, paragraph 31.14, characterises the procedure as follows:

"The super-affirmative procedure provides both Houses with opportunities to comment on proposals for secondary legislation and to recommend amendments before orders for affirmative approval are brought forward in their final form. (It should be noted that the power to amend the proposed instrument remains with the Minister: the two Houses and their committees can only recommend changes, not make them.)"

In Committee, I set out at some length the details of how our super-affirmative procedure could work. In her response, the Minister helpfully summarised that the

"procedure would require an initial draft of the regulations to be laid before Parliament alongside an explanatory statement and that a committee must be convened to report on those draft regulations within 30 days of publication. Only after a minimum of 30 days following the publication of the initial draft regulations may the Secretary of State lay regulations, accompanied by a further published statement on any changes to the regulations. They must then be debated as normal in both Houses and approved by resolution."—[*Official Report*, 19/10/20; col. GC 376.]

According to the Library, the last recorded insertion in a Bill from a super-affirmative procedure was by the Government themselves, in October 2017, in what became the Financial Guidance and Claims Act. In Committee, I noted that when they are not doing it themselves, the Government traditionally object to the use of the super-affirmative on all or any of three grounds. The first is that it is unnecessary, because the affirmative procedure provides sufficient parliamentary scrutiny; the second is that it takes too long; and the third is that it is cumbersome. The Government did not depart from tradition. In Committee, they used all three objections.

The first objection, that the affirmative procedure provides sufficient scrutiny, is plainly and simply wrong, unless of course the Government regard no effective scrutiny as sufficient. The second objection, that it

takes too long, is to misread its purpose. It is the case that the super-affirmative procedure takes longer, but that is because it contains provisions for real scrutiny, which necessarily takes time. This is not a negative; it is the merit of a procedure and the point of it. I should point out here that any emergency or urgent need will not trigger the super-affirmative procedure. The Bill now allows for the "made affirmative" procedure to be used in such cases.

The third objection raised by the Minister was that the super-affirmative procedure could be cumbersome and involve a disproportionate use of parliamentary time. She gave the example of the minor change to the Human Medicines Regulations 2012 to illustrate the point. This was a very helpful observation, and we are grateful for it. It would obviously be wrong to take up parliamentary time on minor changes, but, accordingly, we have revised our amendments since Committee to take account of this. The amendments now before us apply the super-affirmative procedure only to regulations that introduce what the Secretary of State considers to be either significant new policies or significant changes to existing policies. All other SIs can be dealt with as currently specified in the Bill.

This is a skeleton Bill. The noble Lord, Lord Hodgson of Astley Abbotts, chair of our Secondary Legislation Scrutiny Committee, had something to say about this type of Bill in a 4 January article in *Prospect* magazine:

"First and foremost, parliament should continue to be vigilant about the balance of power that is at the heart of our constitution. The right of the legislature (parliament) to resist any encroachment on its powers by the executive (government) is central to our democratic system. … parliament should continue to object to the use of 'skeleton bills.'"

He proposes that the Government:

"Put the appropriate level of detail into primary legislation and avoid skeleton bills."

It is obviously too late to do that with this Bill, which allows Ministers to take powers and make policy before they have decided what that policy is. Secondary legislation was never intended as a means of making policy. Using secondary legislation to do that, as the noble Lord, Lord Blencathra, so clearly put it, bypasses Parliament.

Our proposal restores a measure of parliamentary scrutiny where there are proposed significant new policies or significant changes to existing policies. It is activated only by significant policy changes. It amounts to meaningful scrutiny without removing the final decision from Ministers. It does not get in the way of emergencies or urgent need, but it does prevent Parliament being bypassed. This is an important test of the balance between the Executive and the legislature and an opportunity for Parliament to assert its right, and its duty, to scrutinise. Subject to the Minister's response, I intend to test the opinion of the House. I beg to move.

Lord Judge (CB) [V]: My Lords, I apologise to the House; this is the first time I have spoken on this Bill and I have not been able to speak earlier in the proceedings, so I will try to be brief. I also assume that, notwithstanding the recent vote on sunset clauses, the Minister's response during the debate indicates that the Government will not be very interested in leaving it in the legislation.

This Bill's importance is obvious. It is hardly regulation light; to the contrary, in the modern way, it has a banquet of regulation-making powers which would, as the debate has shown, enable the Minister to extend policy and create policy by statutory instrument. For that purpose, I need simply refer to the observations of the noble Lord, Lord Patel, in the previous debate.

In the 30 December debate on the Bill on the trade agreement with the EU, I suggested that, now that all that was done finally, we in this House at any rate needed to focus on the sovereignty not of the Prime Minister or the Executive but of Parliament over the Executive, and proper parliamentary control over the legislative process. We are, as has been discussed, no longer bound to implement EU directives—hence, in part, this Bill. We should decide now—and if not now, when?—to brake, or at any rate better to control, the damaging, wide-ranging, regulation-making powers which now regularly come our way.

Time and again, the cross-party committees of the House have complained about, for example, skeleton Bills, Henry VIII powers and inappropriate delegated powers. Time and again, in Bill after Bill, the pleas—convincing, constitutional and persuasive—have been totally ignored. A cascade of regulation-making powers continues its unabated flood in every Bill that comes before the House, and this Bill is such an example.

That is not the end of it. The consequences are vividly described in the report of the Secondary Legislation Scrutiny Committee, dated 17 December 2020, just a few days before Christmas. It contains devastating criticisms of risks to proper scrutiny currently observed by that committee. I commend its reading to the whole House. In the first year of this Session, we had 901 statutory instruments. Of those relevant to this Bill, the number from the Department of Health alone was 126. No one in the report has suggested that the department's work is exempt from its wide-ranging, broad criticism.

The wider use of the super-affirmative process would ensure better parliamentary scrutiny and control of the Executive, which for too long have simply ignored the constant urgings of the parliamentary committees in this House, in particular, as this Bill shows, the recently expressed concerns of the Constitution Committee and the Delegated Powers Committee. One day they will ask why they bother. They do so only in the hope that, one day, the Executive of the day will take notice.

As these pleas have been ignored and have failed, and, as is perfectly plain, as I indicated at the outset, the Minister's reservations and distaste for consolidation and sunset clauses were absolutely manifest, this amendment will secure that, for this Bill and for this department, with these wide-ranging and important powers, the super-affirmative level of control should be exercised. The time to exercise it is now. It is time that the power is exercised more frequently.

4.45 pm

Baroness Andrews (Lab) [V]: My Lords, it is a pleasure to follow the noble and learned Lord, Lord Judge, and his magisterial assertion of parliamentary sovereignty, which I entirely agree with. I am pleased to support the amendments in the name of the noble

[Baroness Andrews]
Lord, Lord Sharkey; at the same time, I apologise to your Lordships' House for not having been able to do so in Committee.

In his opening statement on this amendment, the noble Lord made an irresistible case in principle, as well as explaining with great clarity the process by which a super-affirmative order enables effective parliamentary scrutiny in a way that the simple affirmative procedure—however the Government argue it—cannot. In using it, the implementation of this extremely important Bill becomes a less risky and unpredictable affair.

On Second Reading, I said that the Bill was good in many ways but that, as a skeleton Bill, it created unnecessary risks. Despite the Government's amendments and their very recent and welcome response to the DPRRC's scathing report—I am very pleased to say I am a member of that committee—they have still not strengthened the process of parliamentary scrutiny in such a way that should satisfy either the DPRRC or this House.

It is worth reflecting that our wrath as a committee was directed as much at the casual flimsiness of the reasons offered and the false dichotomies between primary and delegated legislation that were set up as at the sheer and extraordinary sweep of the powers across the whole fields of medicine and veterinary science. "Free rein" was one of the milder terms the committee used. Failing at least to take the option of a super-affirmative procedure on these delegated powers still in effect gives the Government free rein. We would be able to challenge the statutory instruments but not change them, however strong the grounds, weighty the evidence or serious the anxieties and risks.

It is significant that, in their response to the committee published this week and in their amendments, the Government recognise that there are risks in the breadth of the powers, but to remove those risks they have merely tightened focus, improved transparency in some cases and assured us that those who use the powers will do so with great care. While any movement was welcome, the Government have refused to acknowledge what is right and proper here—as both the noble Lord, Lord Sharkey, and the noble and learned Lord, Lord Judge, have said, and as the committee made clear—which is a way to engage with and not bypass Parliament.

While under many circumstances the affirmative order is accepted as an appropriate level of scrutiny, it is most certainly not in this case, particularly when the Government choose not to accept that the powers were designated as inappropriate in the first place by the scrutiny committee. A super-affirmative order at least gives Parliament the opportunity to press for further thought, advice and amendment as initiated by the Government. As the noble Lord, Lord Sharkey, said, the amendment has been trimmed so that it deals only with significant changes. This is hardly revolutionary; it is in fact the least that one could insist on, but it is significant. It acknowledges that risks persist but can be reduced and that changes are made to prevent perverse consequences. Surely, in a Bill of this significance, that cannot be too much to ask.

The arguments that the process is too long, slow and cumbersome were dealt with by the noble Lord, Lord Sharkey, in Committee and today. They are but the most recent reiteration of the arguments we hear all the time when we put the case for primary legislation in the face of inappropriate delegation, where speed and technical detail are usually deployed frivolously. They are hardly powerful or relevant when considering the scope of these regulations.

I regret to say that, in their short career, this Government have shown in different ways that they do not welcome interrogation and fear scrutiny. A confident Government would welcome both as a way of avoiding mistakes and creating precedents which in Opposition they could not change. This is a modest opportunity to strengthen this Bill and I hope the amendments will secure the support of the House today.

Lord Naseby (Con) [V]: My Lords, I disagree with this amendment. I had the privilege of being the Chairman of Ways and Means and Senior Deputy Speaker in the other House from 1992 to 1997—possibly, legislatively, one of the most challenging periods. I certainly found that MPs were highly creative in their interpretation of the rules of debate and in holding the Government to account.

Noble Lords have only to read *Erskine May* to see that we have two procedures for SIs that are normal and have been with us for decades: the negative procedure, where no amendments can be taken in your Lordships' House; and the affirmative resolution. The affirmative resolution is not just a weak tool that puts us on the side; it is a very powerful tool if used properly by Members of Parliament and those of your Lordships' House who take an interest in these matters. They can ensure that the Government of the day have to listen.

Frankly, I find that the super-affirmative procedure does no more, really, than involve an additional stage of scrutiny where Parliament has considered a proposal for a statutory instrument before the statutory instrument is formally presented. Today this procedure is used for statutory instruments that are considered to need a particularly high level of scrutiny. Quite frankly, we have Select Committees, in the other House in particular, dedicated to particular departments, and there is a very active Select Committee on health matters.

In addition, yes, there are some specialised categories of statutory instruments that are used for those particular purposes, and they can be considered under the super-affirmative procedure. But these statutory instruments usually amend or repeal Acts of Parliament. Examples would include legislative reform orders, localism orders, public bodies orders, regulatory reform orders and remedial orders. It is not usual to have them as part of the primary legislative process.

It is time that we as politicians understood that this country will be successful only if we get on and understand the needs of British industry. It has to have some certainty that things are going to proceed at pace, not be delayed even further because some noble Lords feel that they want to have another bite of the cherry. We already had quite enough bites, in my judgment, on this Bill as we worked through it, and it is being done very thoroughly. It has been done in Committee and is being done on Report. But we have to understand that this all adds to delay and, even worse, possible confusion in the commercial world.

I think adequate procedures are already available. All this does is stretch the thing out for very little marginal benefit. I personally will vote against this proposal with enthusiasm.

Lord Hunt of Kings Heath (Lab) [V]: My Lords, I must say that I very much disagree with the noble Lord's remarks. If we want certainty, we need legislation that is well grounded and which has had thorough scrutiny in Parliament. The problem with this Bill is that it essentially gives a blank cheque to Ministers to change the regulatory regime for medicines and medical devices. If this was just to deal with the aftermath of Brexit, that, of course, would be understandable. But it was made clear in Committee and at Second Reading that the Government are wedded to this way of doing legislation. As the Minister said in Committee,

"this is a modern and fast-changing industry … we may still need to preserve our ability to amend and update regulations."—[*Official Report*, 19/10/20; col. GC 328.]

The noble and learned Lord, Lord Judge, referred to two of our most distinguished Select Committees. We need to return to what our Constitution Committee said:

"This is a skeleton bill containing extensive delegated powers, covering a range of significant policy matters, with few constraints on the extent of the regulatory changes that could be made … The Government has not provided the exceptional justification required for this skeleton approach."

As the noble and learned Lord, Lord Judge, has said, the Government have form. We are increasingly seeing the use of skeleton Bills and Henry VIII clauses. We really must come to a point where we say to the Government that we will not put up with this any longer.

I listened to the Minister in the last debate: what did he offer the House in respect of further scrutiny? It seemed to me he offered a debate or two, and that was it. The Government do not have an answer; they are refusing to budge on a principle which I believe is fundamentally wrong.

The noble Lord, Lord Naseby, talked with joy about the effectiveness of affirmative statutory instruments. This is nonsense. I think eight SIs have been defeated in your Lordships' House in history; the last one led the Government to threaten to abolish the House of Lords. Unfortunately, the affirmative procedure is hardly any better than the negative procedure, and they do not allow this House to really exert any change on the orders going through.

We have to stand up on this matter. It is much more important and much wider than the issue of medicines regulation. I very much support the amendment moved so effectively by the noble Lord, Lord Sharkey.

Baroness Jolly (LD) [V]: My Lords, these amendments, led by my noble friend Lord Sharkey with eminent cross-party support, replace the affirmative procedure for delegated powers in the Bill with the super-affirmative procedure.

Because of the skeleton nature of the Bill, outlined in the previous group, it is key to ensure that Parliament is able to properly scrutinise regulations made under the Bill. The super-affirmative procedure, which affords a committee of either House the opportunity to comment on a draft of the regulations and make representations, is in our view the best way to do it.

The past year has made clearer than ever the need for outward-facing health policy with public health and safety at its heart. The regulations brought forward under this Bill are central to doing this, and the highest level of scrutiny is needed to ensure their success.

One of the first things I had to learn when joining the House was the sovereignty of the House. My 10 years in your Lordships' House have taught me to spot Henry VIII powers and call them out. As the noble Baroness, Lady Andrews, said, these amendments are hardly revolutionary, so I urge the Minister to accept them.

We need well-grounded legislation, and this Bill gives the department carte blanche to do what it likes. The amendments tabled by my noble friend give Members of the House the opportunity to scrutinise in a proper way and that, after all, is what the public expect of us.

Baroness Thornton (Lab): The noble Baroness, Lady Jolly, and I are not in a competition about who can speak most briefly, but we have promised the Minister that we will—I overshot my promised three minutes by a minute in an earlier speech.

I say from these Benches that we will support this amendment and we are very pleased to be doing so. I reread the debate and discussion in Grand Committee, and I was actually so impressed with my remarks that I am nearly tempted to read them out again, but I will not do so. I also have to say that the whole debate was very good and important.

As my noble friend Lord Hunt says, this is not just about this Bill; this is about how the Government intend to move forward in terms of legislation and policy and subject themselves to appropriate scrutiny. That is what this amendment is about, in our view, and that is why we will support it.

Lord Bethell (Con): My Lords, I am afraid I will breach the convention on short speeches, but only because this has been an incredibly powerful debate. The points were made very thoughtfully, and I am grateful for the fact that they were made briefly. I want to tackle them head on and perhaps, I hope, persuade the noble Lord, Lord Sharkey, to back off from these amendments.

5 pm

The noble Lord, Lord Sharkey, suggested in Committee and again during discussions in December that we would return to this issue of procedure, which he has now done through the amendments in this group. I am extremely grateful to him for the advance warning, although I have to say that our positions are at some distance.

Amendments 3, 28, 41 and 49 would apply the super-affirmative procedure to the regulation-making powers in Clauses 1, 9, 14 and 18. The noble Lord has reflected the debate in Committee, where we spoke at length about the challenges of the universal application of the super-affirmative procedure without further

[Lord Bethell]
refinement. I am pleased that we agree that there is an issue of proportionality as regards when these powers should apply. I commend his endeavour to make his drafting meet the intended purpose and thank him very much. He has drawn a distinction between what is defined in his amendment as "significant new" policy or significant change to policy, and the rest.

However, the noble Lord has combined Amendments 3, 28, 41 and 49 with Amendments 88 to 90. These remove all use of the draft affirmative procedure from the Bill where alternative procedural arrangements are not otherwise specified in Clause 45(3).

If these amendments were applied together, this would mean that there would be no alternative other than the super-affirmative procedure for the vast majority of the exercises of the powers under the Bill. In effect, all uses of the regulation-making powers, other than in relation to the setting of fees, or civil sanctions, or when in an emergency, would be subject to the super-affirmative because no procedure is specified in the noble Lord's amendment for regulations that do not make significant policy changes. The distinction between the "significant policy" changes as he has suggested in Amendments 3, 28, 41 and 49 is therefore lost when they are combined with the other amendments in his name.

Before I address what this would mean in relation to emergencies, I will bring us back to the practical realities of what use of the super-affirmative procedure would involve. Significant amounts of legislation have yet to be made, where we know it has to be made, right across government. Indeed, it is likely that we have a very full year ahead of us. The former business managers among us know what that means in terms of process.

The super-affirmative procedure requires an additional layer of scrutiny to the draft affirmative. Parliament is given 30 days to consider a draft statutory instrument and present recommendations and representations. A final draft of the statutory instrument can then be formally laid to start its normal draft affirmative process only after that 30-day period has ended. All that could take significantly more than 30 days, since any period when Parliament is adjourned for more than four days is not taken into account in those 30 days. I also ask your Lordships: please remember that this super-affirmative process would be in addition to the existing assurances we have already built into the Bill.

Public consultation will apply to all regulatory changes other than in emergencies. Those consultations are those in which parliamentarians can themselves make comment—or indeed, parliamentary committees, if they feel so obliged. Parliament will be provided with a report every two years. That will allow it the opportunity to express itself, however it wishes to and on matters it wishes to, in relation to how the powers have been and may in future be exercised.

Since the Bill's introduction, the majority of the exercises of the powers in the Bill were already subject to the draft affirmative procedure. We have since made changes to make that process near-universal, with the negative procedure now applying only to regulations about fees and regulations supplementing the enforcement regime for medical devices. We have also heard the recommendations of the Delegated Powers and Regulatory Reform Committee and the Constitution Committee, and have changed the use of the negative procedure to the "made affirmative" procedure when making emergency regulatory changes urgently where there is an imminent risk of serious harm to health.

We have listened. However, the noble Lord's changes go considerably beyond the changes I made in Committee to meet him in the middle between the need for scrutiny and the need for practical legislation-drafting.

I understand that the noble Lord wishes to draw a line between what he might call a "minor" change to regulations and a "significant" change, which he thinks would be better dealt with through a higher level of parliamentary scrutiny such as the introduction of a new stand-alone medical devices regime. However, in attempting to make changes to the legislation to cater for the instances of significant policy, he draws everything else into the same unwieldy process, and does so when we have already sought to provide for the scrutiny and opportunity to influence that he seeks, in a more flexible way. If Parliament wants to take a view on legislative changes before they are made, it can, based on the amendments on public consultation already provided for in Committee. But it is not obliged to. That is our difference of opinion: that we should not be subject to an unduly restrictive process when the critical feature that the noble Lord wishes to see built into the Bill is not the timeframe, nor the specifics of the process, but a way of ensuring that there is an opportunity for Parliament to express a view at a point in time when the policy behind any changes is in development. That is already provided for.

The noble Lord has form in asking us to define terminology. He has presented us with a specificity without definition. It is unclear who would make the determination of what a "significant" policy change would be. Nor is it clear what "significant" would mean, and to whom. Indeed, how could we or anyone arrive at an objective test? Without such clarity, uncertainty would compel the application of the super-affirmative process, and we return to the difficulty of applying bulky procedure to matters where being deft and quick is essential. There is a real risk that the most urgent of changes would be ensnared by the super-affirmative procedure without a clear and unambiguous distinction on when the higher threshold must apply.

However, setting aside definitions of "significant", removing the draft affirmative procedure from the Bill entirely would apply the super-affirmative without distinction. Let me give one example of what that would mean. It was necessary in December to make an urgent regulation to accommodate the coronavirus and influenza vaccination rollout, as we identified issues with the regulation. I do not think noble Lords would disagree that proactive regulation of that kind is helpful to all of us when it comes to an emergency situation. But even this would be subject to the super-affirmative procedure if the noble Lord's amendment were to be carried.

It simply does not make sense to apply such a procedure when all the other safeguards in the Bill are in place to guarantee consultation, to ensure that views are heard and to ensure that Parliament can exercise its rights to be heard as freely as any other party.

I understand the arguments about parliamentary scrutiny. However, I strongly maintain that the Bill as amended in Committee strikes the right balance between effective challenge and scrutiny of our regulations, and is workable legislation. I hope the noble Lord has now received sufficient assurances, as well as understanding the challenges inherent in his proposed approach, and I hope that he will feel able to withdraw his amendment.

Lord Sharkey (LD) [V]: I am very grateful to all those who have spoken in support of these amendments. Skeleton Bills always limit parliamentary scrutiny, and this Bill is no exception. The Minister in his more than three-minute speech has exaggerated enormously the difficulties with the reach of our proposal. I disagree, for example, with the notion that our proposal blocks the use of the "made affirmative" procedure. It is clear that the Government are wedded to the idea of taking powers to make policy before they have decided what that policy is, and that is at the heart of the matter. This inevitably means bypassing Parliament and we should resist. I would like to test the opinion of the House.

5.08 pm

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5.21 pm

The Deputy Speaker (Baroness Henig) (Lab): We now come to the group beginning with Amendment 4. 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 the debate.

Amendment 4

Moved by ***Lord Bethell***

4: Clause 1, page 1, line 9, leave out subsection (2) and insert—

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

Member's explanatory statement

This amendment provides that the appropriate authority's overarching objective in making regulations under Clause 1 must be safeguarding public health.

Lord Bethell (Con): My Lords, one of the key qualities of this place is bringing to bear years of expertise in refining legislation. From those involved in life sciences to ex-Health Ministers, we have between us cumulative decades of experience. In moving this amendment, it may be convenient if I speak also to Amendments 6, 8, 9, 11, 29, 30 to 33, 42 to 45 and 47.

I am very grateful to all noble Lords who spoke at Second Reading, who have written, who have met with me and who spoke in Grand Committee on the fundamental points that we are discussing now through Amendment 4: how we ensure that we have the powers needed to make regulatory changes to the bodies of law that govern medicines and medical devices; how we ensure that the changes are swift and safe, and support the continued availability of medicines and devices; how we ensure that essential changes are practicable in a fast-paced environment; and how we provide confidence in the checks and balances built into the framework in which these powers can be exercised.

The amendments that I have tabled are the result of detailed talks. I pay tribute in particular to my noble friend Lord Lansley, the noble and learned Lord, Lord Woolf, and the noble Baroness, Lady Thornton. Their amendments in Grand Committee can be seen as the seeds from which my amendments have grown. I say "my amendments" but I view them as a collective effort—an evolution from our discussions in Grand Committee and refined through cross-party conversation. I will come to and address the noble Baroness's amendments to my amendments, where I hope I can provide further assurances.

As I have said before, this Bill is a framework Bill. It is so because we must have powers that allow us to work with the comprehensive and established regulatory regimes that already exist. We must also have the means to respond effectively, swiftly and appropriately to questions asked. My noble friend Lord Blencathra and his committee asked us very politely to look again at our drafting, and noble Lords suggested that the Bill needed to move from a skeleton Bill to a true framework Bill.

Amendments 4, 6, 8, 9 and 11 make a number of important changes to the regulation-making powers in Clause 1. They provide for the overarching objective sought by my noble friend Lord Lansley and the noble and learned Lord, Lord Woolf. When exercising the power to make regulations, they are to be made in pursuit of the objective of safeguarding public health. That provides all the benefits that my noble friend set out in Committee—an objective test. I do not propose to dwell long on this, as my noble friend explained it so eloquently when he proposed his own amendment then.

However, the noble Baroness, Lady Thornton, has put forward Amendment 5, which would alter the wording of that overarching objective. This would amend the objective from safeguarding "public health" to safeguarding

"the health and safety of the public".

This was, as she knows, the original language of the government amendment in Grand Committee. I expect that the noble Baroness is querying rather than pressing us on this drafting. I say to her that, in the spirit of collegiate drafting, we have adopted the language proposed by my noble friend Lord Lansley. He made a good argument in Committee; we have listened. It was repeated during our conversations outside Committee, and we saw this amendment as a product of the whole House rather than simply the Government. I hope that that answers her questions here.

Turning back to the government amendments, they update the considerations that must be given regard to in pursuit of that objective. Noble Lords did not find the clarification of "attractiveness of the UK" clear enough. A number of alternatives were proposed, setting out the sorts of activities that noble Lords thought were good things to promote. My amendment does away with "attractiveness" and supplies a consolidated list of the sorts of activities that we hope the UK will be seen as a favourable place to undertake. This is absolutely in line with the Government's intention to support the life sciences sector that we have now and to encourage innovation and interest in the UK as a good place to do business in future.

Among others, my noble friend Lady Cumberlege, the noble Lords, Lord Patel and Lord Hunt of Kings Heath, and the noble Baroness, Lady Thornton, made salient points about the importance of safety. While there has never been any intention that making the UK attractive to the life sciences sector should make patients less safe, we have provided for a clear and unambiguous lock on patient safety—that is, as part

[Lord Bethell]
of the decision-making process behind regulatory changes, if proposed changes have an impact on the safety of human medicines, the appropriate authority may make those changes only if the benefits outweigh the risks.

This is very clear. There may, as I said earlier during the Bill's passage, be instances where we do need to make changes that deregulate to ensure the supply of medicines. We have made changes to address the rollout of a vaccination programme; that is absolutely the right thing to do. It requires an assessment of the risks by the experts and requires the benefit—a benefit that the noble Lords who spoke to me at length on this agreed was present—to outweigh the risks. Equally, there is regulatory change that may have no impact at all on safety.

In Amendments 12, 34 and 48, the noble Baroness, Lady Thornton, presses me on the criteria for making this assessment of risks and benefits and on whether the Government will publish that assessment. On the latter point, I can assure her that the amendments made in Committee entirely provide for this. We have already committed to publishing our initial assessment of proposals when we go out to public consultation. That will be the first exposure of our thinking on all aspects, not just risks and benefits. It will be open for persons who respond to that consultation to disagree with us. On the basis of that consultation, we will publish an Explanatory Memorandum when we lay the regulations. There will be ample opportunity to check our homework.

On the criteria, it will not be news to the noble Baroness when I talk of the challenge of specifying a single set of criteria that could apply for the assessment of the risks and benefits of all changes, when regulations may make vastly different changes to the existing regimes. I know that we spoke about these issues with other noble Lords during the discussions preceding Report. I simply do not think that this is necessary or helpful. When the Secretary of State makes amending or supplementary regulatory changes, the Minister will take advice, including from the host of experts inside the MHRA and the VMD, whose day-to-day responsibility it is to protect safety. We have all heard from the excellent Dr June Raine on the importance of safety. It makes sense to take a sensible approach to assessment, particularly in the light of the fact that we will set it out in the ways I have spoken to.

I am very pleased that we have arrived at a formulation that works. It is practicable and good legislation at the same time. Amendments 29 to 33 repeat this set of changes in relation to the regulation-making powers at Clause 9 for veterinary medicines—with an important distinction. The difference relates to how the overarching objective is formulated. This reflects the material differences and choices made for the regulation of veterinary medicines, such as reserving certain medicines for use in humans to avoid further antimicrobial resistance. It is right that we have an objective but that that objective works in this context. It is also right that the same lock on safety is applied.

Amendments 42 to 45 and 47 would apply the same framework to the regulation-making power in Clause 14 in relation to medical devices. When making amending and supplementary changes to the regulation of devices, it provides a separate but similar list of activities that we would wish to be seen as favourable, including the addition of carrying out research on medical devices. In the light of our debate in Committee and the debate we have ahead of us on the importance of medical technologies, this inclusion is absolutely right.

I do not propose to take significant time speaking to Amendments 73 and 94. They both make minor changes, but for an intent with which I do not think any noble Lord would disagree. In the interests of clarity, Amendment 73 would require a consultation on regulations under Clauses 1, 9 or 14 to include a summary of the assessment of the person making the regulations of all matters mentioned in these clauses. Amendment 94 serves to clarify the commencement of the definition of "human medicines provision" at Clause 5.

5.30 pm

I hope I have demonstrated the Government's willingness to listen and determination to get this right. I am very grateful to noble Lords for their commitment, and for the spirit with which they have approached our discussions on these matters. I think we have arrived at very good and practicable legislation, which is essential. I hope the noble Baroness is sufficiently assured, so as not to press her amendment. I beg to move.

Amendment 5 (to Amendment 4)

Moved by ***Baroness Thornton***

5: Clause 1, leave out "public health" and insert "the health and safety of the public"

Member's explanatory statement

This amendment provides that the appropriate authority's overarching objective in making regulations under Clause 1 must be safeguarding the health and safety of the public.

Baroness Thornton (Lab): As I said to the noble Lord and the Bill team yesterday, these are probing amendments and I do not have any intention of pressing them. That is because I accept that the Minister and the Bill team have done a very good job of making this part of the Bill work much better.

It is always worth rehearsing in the Chamber some of the arguments that we have had outside the Chamber, because people often go back to the *Hansard* record to ask why we changed words from this to this. That is why the noble Baroness, Lady Jolly, and I put down some of these amendments. We have had some extremely useful discussions outside the Chamber, as we should have done, so I hope the noble Lord understands that that is why these amendments are being put today.

Under my Amendment 5, the overarching objective in making regulations under Clause 1 must be safeguarding public health. This is a probing amendment on the difference between "public health" in the government amendment before us today and the "health and safety of the public", which was the phrase used in the amendment introduced in Committee. It is worth explaining why we accept that that change was sensible.

It is my understanding that "public health" is a broader and more subjective concept that may encompass economic interests, or may relate to increased pharmaceutical investment and innovation, and other factors beyond health and safety, which may conflict with them in some circumstances. Does the Minister agree that we have to explain the less strong commitment that is included in the Bill? Safeguarding public health is also not the same as protecting the safety of medicines and medical devices. It is very important that we are clear about that in the powers given to the Secretary of State in determining what would contribute to safeguarding public health.

I congratulate the drafters on changing "attractiveness" to "favourability" and "benefits" and "risks" in my Amendments 12, 34 and 48. These amendments seek to probe the criteria that determine whether benefits outweigh risks and require the assessment to be published. The government amendments in this group replace the consideration of UK attractiveness with reference to it being a "favourable" place in which to conduct clinical trials and manufacture and research new medicines, medical products and services. The theme that runs through the whole of this legislation, as has been mentioned by many noble Lords, is that that is the place we want to be in, and the country we want to be, as we move forward.

Proposed new subsection (3A) looks like an attempt to allay concerns, stating that, where regulations impact on safety, they may be made only if the benefits outweigh the risks. It is worth putting on the record the discussion that we had about benefits and risks. Risk and benefit analyses are a well-established feature of clinical trials regulations and ethics committees, but they normally have more well-defined parameters than simply a risk-benefit assessment, yet these are precisely the regulations that these powers will allow to be made. This is why we need to make sure that we are clear what we are talking about here. This comes back to scrutiny and the need for the ability to scrutinise the Government's assessment of risks and benefits in making regulations. These arguments pertain to Clause 9 for veterinary medicine and Clause 14 for medical devices. That is why we wanted to have this discussion.

Lord Sharkey (LD) [V]: My Lords, I welcome the amendments in this group. They add clarity to the obligations laid on the Secretary of State in making regulations under Clause 1(1) and its counterparts.

I particularly welcome Amendment 12 in the names of the noble Baroness, Lady Thornton, and my noble friend Lady Jolly, as it seems particularly important. It requires the Secretary of State to publish the criteria used in determining the benefits and risks caused by regulation and to set out how they have been weighed against each other. This amendment touches on the whole issue of transparency in devising regulations. The level of transparency that Amendment 12 requires should certainly apply to the factors listed in the Minister's Amendment 9. These factors, which the Secretary of State must have regard to, are the safety of human medicines, the availability of human medicines and the likelihood of the relevant part of the United Kingdom being seen as a favourable place in which to carry out research related to human medicines, conduct clinical trials, or manufacture or supply human medicines. These are all clearly important, and I am glad that the Minister has added manufacturing to this list, as I suggested in Committee.

The list contains three rather vague notions: "likelihood", "favourable" and "being seen as". For all these terms, we need to know what definitions will be used and what evidence will be required in support. For "being seen as", the question arises: being seen as by whom? What weight will be given to different views from different sectors? If, for example, it turns out that academic researchers and pharma companies have different views about the favourability of the UK, how are they to be weighted? On "likelihood", could the Minister say whether he considered the word "desirability" instead, which seems closer to what we want here?

I hope the Minister is able to give reassurance on the points I have raised and that he accepts the merits of Amendment 12 and its counterparts.

Lord O'Shaughnessy (Con): My Lords, I will make three quick points about the government amendments in this group, which I broadly welcome. The first relates to Amendments 4 and 42, where the Minister has clearly listened carefully to the forceful arguments made by my noble friend Lord Lansley, the noble and learned Lord, Lord Woolf, the noble Baroness, Lady Jolly, and others in Committee. I am delighted that he has.

For those of us who have not been involved in the discussions, and following on from the points that the noble Baroness, Lady Thornton, made about why language from the European regulation has been adopted—"safeguarding public health"—it would be helpful if my noble friend could explain, on the record, why that language has been chosen. That is particularly the case given that he expressed some reluctance in Committee, bearing in mind that the regulations being referred to also had some relevance to operating the internal market, not simply medicines safety. It would be good to hear from him on that.

Secondly, on Amendments 8 and 44, unlike other noble Lords I did not believe that there was a suspect motivation behind the use of the word "attractive" by my noble friend and the Bill team, or any desire to reduce stringency to attract investment. But I would be grateful if my noble friend could confirm that the Government remain as determined as ever, if not more so, to grow the UK's life sciences sector, and that it was never their intention to lower regulatory standards to achieve this.

Thirdly, on Amendments 9 and 45, I commend my noble friend on the subtle but important changes already referred to by the noble Lord, Lord Sharkey, in Clauses 1(3)(c) and 14(3)(c), especially the inclusion of manufacturing and broader medical research. The salience of these two parts of our overall supply chain has come to the fore during the pandemic, which has demonstrated our strengths in basic science but, unfortunately, exposed our weaknesses in manufacturing resilience. It seems right that this should be explicitly recognised in the Bill and I commend my noble friend for making those important changes and for demonstrating, once again, his ample appetite for listening and acting.

Baroness Bennett of Manor Castle (GP) [V]: My Lords, I will save up some of my time for my next amendment, Amendment 7, so I will be very brief. I will chiefly speak to the non-government amendments in this group. It is encouraging that the Government have taken onboard so many of the contributions from Committee, but that shows what an unbaked condition the Bill came to us in.

To address the somewhat related Amendments 12, 34 and 48, all in the name of the noble Baroness, Lady Thornton, we are talking about publication of the data, information and assessment of benefits versus risks. We heard powerfully from the noble and learned Lord, Lord Judge, and many others in the previous group of amendments how great a concern there is about a lack of scrutiny of this whole procedure in the House. Public scrutiny is surely the best scrutiny of all. I commend all those amendments to the House.

Amendment 5 is very interesting. My innate reflex is to go towards public health as a systems-thinking, sustainable development goal kind of approach to looking at the whole. But to build on the remarks the noble Baroness, Lady Thornton, made in introducing the amendment, which is also back by the noble Baroness, Lady Jolly, when we talk about the immensely financially powerful and often very opaque pharmaceutical industry, with its very large multinational companies, we have to worry about what lawyers call equality of arms and the degree to which economic and financial arguments might be deployed in potentially damaging ways. I am interested in the Minister's response to Amendment 5, but I can certainly see the strength of the argument of the noble Baroness, Lady Thornton.

Baroness Cumberlege (Con) [V]: My Lords, I will speak to government Amendments 11 and 47, and those that follow on from them, Amendments 12 and 48 from the noble Baroness, Lady Thornton. The first lot refer to medicines and the second to devices. But first I thank the Minister for his strong emphasis on safety in all the amendments. He certainly has listened to noble Lords. In Committee we stressed the objective of making sure that the Bill is a safety Bill. I believe that safety now permeates throughout the Bill, which is so encouraging, and I thank him and his colleagues for that.

Although I welcome the government amendments, I really do not envy a Secretary of State's task in weighing up the risks versus the benefits. This will require the wisdom of Solomon. At least once the Bill is enacted we will have the data, which is all-important and has just been referred to. Our review's report shone the light on our frustration of not knowing what was happening to whom, by whom, when and where. This will, of course, become apparent, which will be very useful once we have these processes in place.

But we are still left with weighing up the benefits versus the risks. Surely this depends on where the threshold is set concerning any medicine or medical device. For instance, if 99 people benefit from one of these products but one dies, what weight do we give to the 99—or, perhaps more importantly, to the one who died? Does the Minister see thresholds as important? If so, does he envisage the application of a threshold for an individual medicine or device, or would there be a threshold to cover a similar range of products, or indeed a more overriding policy? I am not quite sure how this will be tackled.

5.45 pm

I support the amendments from the noble Baroness, Lady Thornton, because although they would not support the Secretary of State in reaching his decision, they would require talking to patients and a wide range of other people, but also provide some transparency, in that the appropriate authority must publish the criteria and assessment of why the benefits outweigh the risks. This will go some way, I presume, to sorting out this thorny issue of thresholds.

Transparency is, of course, critical to open government and it should be welcomed, but I understand this as being retrospective. Is that right? Is this included in regulations, perhaps, where there will be an important opportunity to debate signal detection to prevent harm, and whether these regulations would be prospective measures? Avoiding harm, rather than actually seeing what has happened in the past, seems much more preferable. Can that be part of this whole exercise of what we will discuss in regulations?

Lord Hunt of Kings Heath (Lab) [V]: My Lords, it is a great pleasure to follow the noble Baroness, Lady Cumberlege. She posed a very tough question to the Minister. I could not help reflecting on her report and the issues around surgical mesh, where we clearly had a situation where for some women the surgical mesh operation was successful and seemed to be effective, but for others it had devastating consequences.

The question of a threshold is surely very important. I doubt very much that the medical device regulation we have is up to dealing with it. It would be good to know from the Minister how the Government will take forward discussions in this area, which of course involves ethical as much as safety considerations. Generally, though, I very much welcome the government amendments. I think that my noble friend's amendments add to the debate.

I have always wanted the UK to be safe in terms of medicine and medical devices and outcomes, but I also want this country to be attractive to pharmaceutical and medical device companies to research, develop and launch their products in the UK. The UK's record in the current crisis, in the development of both vaccines and treatments, is second to none. I hope that it will be a huge boost to our future attractiveness. But as I have raised on a number of occasions, one of the big problems we have in this country is the general slowness of the NHS to adopt new medicines and new treatments. If we really are to be attractive and have a favourable climate, we have to get around that. We have to be seen, particularly post Brexit, as not only a place that has fantastic scientists and clinicians, and a very good science base—in fact, a brilliant one—but where the NHS is itself innovative, forward thinking and keen to use new medicines and treatments. That is a huge challenge. It would be good to hear the Minister respond and spell out how he thinks we can make this country safe, but attractive too.

Lord Lansley (Con) [V]: My Lords, I am pleased to follow the noble Lord, Lord Hunt of Kings Heath, who again has raised an important issue. The amendment in this group which more broadly encompass all those elements that go to make the United Kingdom a favourable location for research and the manufacture and supply of medicines gives us an opportunity to make sure that we have got that right.

I support the government amendments in this group and add my thanks to those expressed to the Minister and the Bill team for the immensely constructive way in which they responded to the amendments that we brought forward in Committee and in many related discussions. At Second Reading, the noble and learned Lord, Lord Woolf, and I were worried that the Bill was skeletal. We wanted to put a bit of flesh on its bones and make it more of a framework Bill—I think that is a bit of a theme. In the spirit of the remarks of the noble Baroness, Lady Thornton, it might be helpful if I briefly explained what we were trying to achieve, and how these government amendments appear to have responded well to that.

First, even following the initial changes, the structure of the powers was not objective; they were that the relevant Minister was satisfied that the regulations met certain requirements. What we were looking for from the outset was an objective test. My noble friend Lord O'Shaughnessy asked what that objective test was and why we chose to continue with the structure of safeguarding public health? The short answer is that it is because that is the objective in the European Union regulation; it is not an objective in that context which relates to the internal market provisions. To have moved away from the objective of safeguarding public health would run the risk of it being interpreted as somehow different from the past objective on the basis of which decisions had been made and regulations pursued. That seemed entirely appropriate as an encompassing and overarching objective for all these related requirements. I am happy that the Government's amendment has taken that forward as an objective measure against which the regulations, the use of these powers, can be tested.

Secondly, we wanted to make sure that safety was built into the structure of regulation-making powers. We had an extremely helpful debate about that, and I think that it was clear that, while we wanted to make safety central to what was being achieved, it would not be appropriate to make it an overriding objective. That would have led to the regulator being required effectively to eliminate risk. That brings me to the point made by my noble friend Lady Cumberlege. We then came to the further question of how, if safety is the issue, we then manage the test of whether benefits outweigh risks, sufficiently so for regulations to be proceeded with. The answer is that the objective is not to eliminate risk; it is to eliminate harm. We must make a distinction between those two things.

Making safety the overriding objective would have meant us having to eliminate risk. At the moment, we balance benefits and risks, not benefits and harms. When my noble friend Lady Cumberlege asked her question, I think she was suggesting that we were having to balance benefits and harms, whereas on pretty much every occasion the regulator is asked to undertake an authorisation they have to balance benefits and risks, because we can never eliminate risk. The question is: can we quantify it? That is what the trials and the data are meant to enable us to do—to quantify the benefits and risks. In making an authorisation, can we make sure that we have avoided harm but at the same time realised those benefits?

These amendments get us to that balance. They enable us to give an objective test against which the powers can be measured; they enable us to put safety clearly at the heart of the thinking about how the powers are to be used, and they enable the regulator to undertake that appropriate measurement of benefits and risks. I support the amendments and appreciate the way in which we have arrived at this place by constructive discussion.

Baroness McIntosh of Pickering (Con) [V]: My Lords, I welcome Amendment 5 and others in this group. I echo the noble Baroness, Lady Thornton, in complimenting both the Minister and the Bill team on their expert handling of this part of the Bill.

I find the sentiment behind Amendment 12 attractive and endorse entirely the words of my noble friend Lady Cumberlege and others who have supported her in wanting to avoid "harm". The idea of a threshold, as solicited in Amendment 12, seems helpful. I have a question for my noble friend the Minister to which I would be grateful for a response. We are told in the explanatory statement that the amendment would require the Secretary of State

"to publish the criteria that will be used by the appropriate authority"—

obviously not yet set up—

"to determine whether the benefits of regulations that may impact on the safety of human medicines outweigh the risk"

and

"to allow for greater transparency and scrutiny."

My noble friend said that the Government intended to publish the initial assessments. It would be helpful to know when that would be.

There currently seems to be a gap in the law; for example, as regards the vaccinations—I know that this was debated earlier today. The Government have unilaterally extended the time between the first dose and the second dose of Pfizer and AstraZeneca vaccines from three weeks—21 days—to up to 12 weeks. No other European country that I am aware of has done this. It is true that Denmark is looking to extend it to a maximum of between four and six weeks, which is nearer the initial three-week period. I presume that, if what is proposed by Amendment 12 were law, the Government would be obliged to publish the arguments in the interests of transparency, openness and scrutiny as to how they had reached that decision. If that were the case, I would be minded to support Amendment 12.

Otherwise, I welcome Amendments 4 and 5 and others in the group, which look to establish the overarching objective as being public health. I like the formulation of words that the Government have hit on and hope that they will stick with it. I shall be interested to hear how my noble friend responds, but, as I see it, there is some merit in Amendment 12.

Baroness Jolly (LD) [V]: My Lords, this has been a fascinating debate. We all want the UK to be a manufacturing centre for pharmaceuticals and valuable medical devices. The amendments in this group relate largely to the overarching objective of regulations made under the Bill.

It was argued in Committee that the Government needed to be clearer about the intent of the regulations and what the guiding principles would be. I am pleased that they have accepted this, and a number of amendments in this group provide that the appropriate authority's overarching objective in making regulations must be safeguarding public health.

The noble Baroness, Lady Thornton, and I put down an amendment to change "public health" in the government amendment to

"the health and safety of the public".

That was not an "angels dancing on the head of a pin" moment. Public health could have a very narrow definition in a health and social care context—we think of local government and Public Health England. However, our wording describes the issue that we are discussing. It is much broader than the "public health" definition, which is too narrow. Health and safety should be at the centre of what is used in treatment. The abuse of this was illustrated by the noble Baroness, Lady Cumberlege, who gave us perfect examples in her report. Mesh is technically a device and sodium valproate was the medicine. They were both abused, and their use was inappropriate. They hurt and damaged a lot of people, predominantly women, for a very long time—some people, for ever.

Now we have a workable framework in which to put both medicines and medical devices in the context of the health of the public, and that is extremely welcome.

6 pm

Lord Bethell (Con): My Lords, I completely concur with the noble Baroness, Lady Jolly. This has been a fascinating debate but I will restrict my comments to a few specifics in answering some of the questions raised by noble Lords. I shall start by talking briefly about risks and benefits, which I hope will provide further reassurances to noble Lords regarding their questions on these points.

A regulatory change that, for example, makes changes similar to those made to ensure the smooth vaccination programme for Covid-19, will require different assessment to those that change the medical devices regulatory regime to step up scrutiny of medical devices. The noble Lords, Lord Patel and Lord Kakkar, spent some time in Committee speaking to the importance of medical device regulation, and I agree with them. The amendments that I have tabled are silent on whether the impact on safety must be negative or positive to have the "lock" kick in. It applies to both.

However, it will come down to what the change is in order to determine what constitutes a risk in that scenario versus a benefit. That is obvious in the case of the Covid vaccine rollout. There is greater benefit to a smooth rollout of the vaccine programme than the risk of increasing the number of healthcare professionals who can deliver it. Risks can be mitigated, and they should be. Changes can also be highly technical. They may affect the safety of medicines or medical devices in a minor way but not to the same degree or extent as other changes. It would be impracticable to develop criteria that apply in all circumstances to all regulatory changes.

In response to my noble friend Lord O'Shaughnessy, I should reassure him that it is not our intention to in any way water down or reduce standards in the life sciences area. Instead, it is our intention to use this legislation to champion the UK's wonderful life sciences sector.

We have often spoken of safety—I thank the noble Baroness, Lady Thornton, for her words on that matter—and of the vital importance of the regulator putting this at the heart of its work. Our regulator is stuffed full of scientists and experts. They are able to support the Secretary of State in making that assessment, based on the evidence. Would this change impact the highly regulated safety considerations, and are they the right ones to make? We need to empower those experts to make those recommendations, in specific circumstances. I hope that noble Lords agree with me that the Bill is better for the changes that we have already sought to make, that the questions behind these further changes are answered, and that we have reached a point of conclusion.

Baroness Thornton (Lab): That debate was definitely worth having, notwithstanding the fact that the noble Lord, Lord Lansley, explained the process that we had gone through when discussing what to do and how to improve the Bill regarding these aspects. They were important discussions. The noble Lord, Lord O'Shaughnessy, asked pertinent questions that the Minister has answered and are now on the record. I thank the noble Baroness, Lady Jolly, for explaining why we felt that it was important to have this discussion. I also thank other noble Lords for their remarks and the support they have given. I beg leave to withdraw my amendment.

Amendment 5 (to Amendment 4) withdrawn.

Amendment 4 agreed.

Amendment 6

Moved by ***Lord Bethell***

6: Clause 1, page 1, line 11, 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 1(2).

Amendment 6 agreed.

The Deputy Speaker (Lord McNicol of West Kilbride) (Lab): We now come to the group consisting of Amendment 7. 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 during the debate.

Amendment 7

Moved by ***Baroness Bennett of Manor Castle***

7: Clause 1, page 1, line 14, at end insert—

"(ba) the protection of the environment;"

Baroness Bennett of Manor Castle (GP) [V]: My Lords, I thank the noble Baroness, Lady Jolly, for her support. This is the survivor of a suite of amendments that I moved in Committee. About half an hour ago I tweeted out the *Hansard* link to that for anyone who is interested, and a link to an article I wrote at that time in the *Ecologist*. The amendments were all about the environmental impacts of medicines and medical devices, including the impacts of packaging.

Responding for the Government, the noble Baroness, Lady Penn, suggested that the environmental issues of packaging, and the issues around medical devices, would be covered elsewhere, notably in the Environment Bill. She did, however, acknowledge the importance of these issues. Some of those amendments related particularly to anti-microbial resistance, and the noble Baroness, Lady Penn, noted that this

"has been placed on the National Risk Register of Civil Emergencies as a 'longer term trend' likely to change the overall risk landscape for the UK over the coming decades."—[*Official Report*, 26/10/20; col. GC 62.]

I think that is an acknowledgement by the Government of the importance of these issues around anti-microbial resistance. But we are starting to see much bigger issues: we have heard and seen the Government acknowledge in other contexts the cocktail effects of drugs and chemically active compounds in the natural environment.

I am not convinced by the argument presented by the noble Baroness, Lady Penn, about the other amendments. Since this is Report, I decided to focus on this one single amendment, for which I think the Government have—unintentionally—made their own case very strongly, by ways which I will come to at the end of my comments.

To briefly set out the case for why the Environment Bill and general environmental legislation will not cover medicines, the fact is that human medicines are highly biologically active substances, that are in the human body and pass through it. The medics will tell you that they need to be at still very high concentrations when they pass out of the human body to ensure that they have medical effectiveness. They are also metabolised in the human body in the natural world, in both anaerobic and aerobic environments. It is highly unlikely that normal legislation about waste—normal environmental legislation—will be able to deal with that, let alone its impact on the human microbiomes, and the microbiome all around us.

If we think of bringing this back to the practical: the manufacturer of baked beans might be regulated about the impacts of the tin or the impacts of consumption on human health, but in normal food safety or environmental health impact assessments, the broader impact of that consumption of baked beans is probably not going to be taken into account.

I am aware that your Lordships' House might find me often citing some fairly technical science, and I am afraid I am going to do it again. Just as one example, I am going to cite a 2018 article from *Frontiers in Microbiology*. The title of the article is "Antibiotic Effects on Microbial Communities Responsible for Denitrification and N2O Production in Grassland Soils." Your Lordships' House might note that I have been spending lots of time at the Oxford Real Farming Conference recently.

To quote from that article, it says that

"the acute effects of tetracycline on soil microbial community composition and production of nitrous oxide … and dinitrogen … as the end-products of denitrification"

are

"an increase in the fungi:bacteria ratio and a significant decrease in the abundance"

of bacteria carrying a certain gene. Those who follow these issues will know that that has significant climate change impacts, but it also has very serious soil impacts.

Before I make my next comments, I should perhaps declare my membership of the APPG on Human Microbiome. The human microbiome that we have on our skin, in our lungs and in our gut also has impacts on the microbiome all around us, and the medicines that we take have an impact on both of those—that is, the microbiome of everything from bees to bats. Perhaps Covid-19 will help us understand the complexity of the systems that we are dealing with.

The fact is that past generations have left us with a poisoned planet. Historically, various diseases were treated were mercury. Many poisons have also been used as medicines, and of course many chemicals were used and are now widespread in the environment and are having enormous impacts. A story came out this morning about the fertility of male porpoises living off the UK being affected by polychlorinated biphenyls—PCBs—which were phased out decades ago but are still having impacts today. We are talking here about systems thinking.

I believe that the Government are, unintentionally, making their own argument for this amendment. I point noble Lords to page 6 of the Bill and Part 2, Chapter 1, covering veterinary medicines. Clause 9(2)(c) refers to

"the protection of the environment."

Here, we are talking about the authority that makes the regulations on veterinary medicines having to be sure that it promotes the protection of the environment.

On page 1, we find the almost matching subsection under Chapter 1 on human medicines. The first two paragraphs of Clauses 1(3) and 9(3) are the same, then Clause 1(3)(c) goes on to talk about the UK being

"an attractive … place in which to conduct clinical trials or supply human medicines."

But there is something missing—words about protecting the environment.

Therefore, with this amendment I have chosen simply to take the Government's own words, as used in the part of the Bill on veterinary medicines, and say that we have to apply the same oversight and approach to human medicines as to veterinary medicines.

[Baroness Bennett of Manor Castle]

I come back, as this debate so often has done, to the brilliant report of the noble Baroness, Lady Cumberlege, *First Do No Harm*. I would say that the Government have accepted that principle in putting the clause on environmental impacts in the veterinary medicines section of the Bill. I really cannot see how they can justify not doing the same for human medicines.

I have previously called only one vote in your Lordships' House—on what one might call the "grand matter of principle", which was about freedom of movement—but at the moment I am feeling very inclined also to call a vote on this amendment. We are in a situation where our planet is at its limits—right at its edge. We are all on the edge: our life is on the edge. We cannot keep saying about the environment, "Oh, we'll include that in a nice little silo in the Environment Bill." We have to look at the impacts of everything that we do. The impact of human medicines on the environment is significant, as is the impact of veterinary medicines.

I will listen very carefully to what other speakers and the Minister have to say, and I shall be very interested in hearing the Minister's explanation for the veterinary medicines and human medicines sections of the Bill being different. However, at the moment, I am certainly inclined to test the opinion of the House on this amendment. I beg to move.

Baroness Masham of Ilton (CB) [V]: My Lords, I thank the noble Baroness, Lady Bennett of Manor Castle, for tabling this very important amendment. For a long time, I have been interested in the growing resistance to antibiotics. The residue of many of them, used for both humans and animals, pass into the environment by different routes. One route is through sewage, which is then processed and goes back into the land where animals graze, and then enters the food chain. Flooding causes contamination and can cause infections through escaping sewage, and this can give rise to environmental and public health matters that need addressing.

6.15 pm

There is also an environmental problem of contamination of the river courses by industrial waste, leachate, pesticides and fertilisers, which can cause fish to die. Contamination of fresh water by rats' urine poses an environmental public health risk as it causes Weil's disease, also known as leptospirosis, which can be fatal. Rats and mice can also contaminate food. Increased asthma and respiratory disease due to poor air quality is another environmental problem. There should be an effective, well-funded public health system, which works in conjunction with the environment and agricultural organisations. Prevention of disease and the safety of the environment are of extreme importance.

Baroness Jolly (LD) [V]: My Lords, this amendment would require the appropriate authority to have regard to the protection of the environment when making regulations about human medicines. We have left the EU and need to be sure that our replacement regulations are fit for purpose. Many of us have spent a lot of time checking that these replacements are in such a fit state; but, while the health and safety of patients remain paramount, it is reasonable and, indeed, important, given the climate crisis, to consider the environmental implications of any policy stemming from these regulations.

The manufacture of human and veterinary medicines, and medical devices, does not happen in an environmental vacuum. Manufacturers have a duty to protect their environment—and manufacturers of medicines will need to be open about how they deal with chemical and other waste. I live in Cornwall where oestrogen has found its way into local rivers, ecosystems and oysters. Wastewater from pharmaceutical manufacturers could also find its way into local waterways. Will the Minister outline how this is dealt with by regulators, and how it is covered by the Bill?

Much waste from pharmaceutical plants is toxic and dealt with appropriately by manufacturers but, in a Brexit world, the regulation regime will have different regulations from the very strict ones that applied when we had to follow EU regulations. We can buy our medicines and medical devices from all over the world; we know that not everyone has the same high environmental standards governing manufacture that we have. What criteria are appropriate in the commissioning and purchasing of medicines from the rest of the world? Can the Minister please outline for us the nature of discussions with regulators about these issues?

Lord Hunt of Kings Heath (Lab) [V]: My Lords, this debate follows a very interesting one in Committee, in which the noble Baroness, Lady Bennett, posed some searching questions about the potential for designing new drugs that are less harmful for the environment, whether in their composition, their impact when they escape into the environment, or in their packaging. Today, she also argues that the expectation of this approach should be built into legislation.

In Committee, the noble Baroness gave some very interesting examples. I was particularly interested to hear that in Sweden—

The Deputy Speaker (Lord McNicol of West Kilbride) (Lab): We appear to have lost connection with the noble Lord, Lord Hunt. We will give it a few seconds. We have now reconnected but we missed about 30 seconds of his speech; perhaps the noble Lord could take us back about 30 seconds.

Lord Hunt of Kings Heath (Lab) [V]: I thank the noble Lord; that is a temptation to be eagerly accepted. I was referring back to what the noble Baroness, Lady Bennett, said in Committee and the example in Sweden of Stockholm county council, which grades medicines on their environmental effects. Doctors can choose to prescribe a drug that is less harmful in relation to the environment where that option exists.

We have also had the 2014 report by UK Water Industry Research, which found that in most of the 160 sewage treatment works studied, several common drugs were present in the final effluent in concentrations high enough to potentially affect ecosystems. The noble Baroness, Lady Jolly, referred just now to the amount of pharmaceutical effluence entering waterways,

and according to a 2018 study by the Delft Institute for Water Education, that could increase by two-thirds before mid-century.

In Committee, my noble friend Lady Wheeler referred to the Environment Agency also having found examples of contaminated hospital waste being illegally exported to developing countries such as Malaysia for disposal. What steps are we taking to prevent the illegal export of such waste and ensure that we dispose of our own waste in this country? There are also concerns about the use of incinerators for hospital waste and the health impacts on those living nearby. We must ask whether the Government are doing enough to ensure that chemists and GPs' surgeries provide a secure depository for unused medicines, so that they do not contaminate the water supply by being washed down the sink or ending up in landfill.

The noble Baroness, Lady Bennett, said today that the Government's approach has been to say that legislation is already on the statute book regarding the impact on the environment more broadly, including legislation to address the impact of producing and disposing of manufactured goods such as medical devices. But there is a persuasive argument that we should go further and that it is appropriate that in this Bill on medicines and medical devices there should be a way of ensuring that the environmental impact is not a damaging one. I hope that the Minister can respond with a positive reflection that this is an area that needs further exploration.

Baroness Penn (Con): My Lords, when considering Amendment 7, tabled by the noble Baroness, Lady Bennett of Manor Castle, I draw the attention of noble Lords to our earlier discussion on the government amendments to this clause, introducing the requirement that safeguarding public health is the overarching objective when making regulations. The clause sets out a number of important factors that the appropriate authority must have regard to, and it is important to note that this is by no means a closed list of factors to be taken into account when making regulatory changes. I recognise that the intention is to put this important issue at the forefront of our minds, and that the factors involved in environmental protection, while broader than the remit of this Bill, may indeed be relevant as something to have regard to—and in those situations, this will happen. Let me explain.

In Committee, the noble Baroness raised important points about tackling the causes of environmental damage and listening to relevant stakeholders. As she knows, the Bill now includes Clause 43, which states that a public consultation must be carried out before regulations are made. This would provide an appropriate platform for relevant stakeholders in the production, distribution and consumption of human medicines, including manufacturers, healthcare practitioners and patients—and the noble Baroness will surely think also of campaigners—to raise their concerns and provide suggestions regarding regulations, which may include factors involving environmental protection. We would all agree that considering the environmental impact of what we do is important, but the power in Clause 1 is restricted to amending and supplementing the law relating to human medicines.

However, as I have reassured the noble Baroness previously, that law does not stand in isolation. The regulations made under this Bill must be considered within the wider context of other existing legislation that makes provision for environmental protection and access to medicines and healthcare services. The collective picture of legislation across the statute book ensures that environmental concerns are taken seriously. It includes provisions around packaging, safe management of medicines waste and medicines disposal. An example is the Environmental Protection Act 1990, which makes provision for the safe management of waste. This Act, which must be complied with by community pharmacies, imposes a duty of care on any person who disposes of controlled waste to take all reasonable steps to ensure that it is not disposed of in a manner likely to cause pollution of the environment or harm to human health.

I also reassure the noble Lord, Lord Hunt, on that point with regard to the management of waste and the noble Baroness, Lady Jolly, on the fact that the Government have made a clear commitment that, post Brexit, our environmental standards will not be reduced. As the noble Baroness, Lady Bennett of Manor Castle, pointed out, the upcoming environment Bill will be a further opportunity to debate many of those matters in detail.

On the question put by the noble Baroness, Lady Bennett, of why the environmental impact of veterinary medicines has been included in the Bill, whereas the environmental impact of human medicines is not specifically provided for, the situation with veterinary medicines is slightly different. The environmental safety aspects of the regulatory framework on veterinary medicines relate to their potential impact on the terrestrial and aquatic ecosystems and their flora and fauna—soil, micro-organisms, fungi, algae, plants, invertebrates, fish, et cetera—so veterinary medicines occupy a slightly different space in our regulatory framework. I also point out to her that animals receiving veterinary medicines form part of the human food supply chain, so that is also taken into account.

I hope that the noble Baroness has heard sufficient from me to be persuaded that, while the issue of environmental protection is of course vital, the law in this area is already well established and, in the light of this, that she will feel able to withdraw her amendment.

Baroness Bennett of Manor Castle (GP) [V]: I thank the Minister for her answer and the noble Baroness, Lady Masham of Ilton, for her support for the amendment and her full reflections on the importance of antimicrobial resistance—something that we will be talking about a great deal in the coming years. The contribution of the noble Baroness, Lady Jolly, was also hugely valuable, in that she complemented by looking at aspects that I had not taken up. She mentioned manufacturing not happening in an environmental vacuum, and in particular the issue of hormones such as oestrogen, and also focused on imported medicines and medical devices and their global impact—something that I talked about in Committee but had not talked about tonight.

[Baroness Bennett of Manor Castle]

I thank the noble Lord, Lord Hunt, for his interest in and attention to what I said in Committee, and for his patience with the technology. I will take what he said as something of an expression of support for the intention behind this amendment.

I have two specific questions to press the Minister on further. She spoke about the processes of overseeing production and distribution, but she did not refer to, and was apparently not thinking about, issues around how research is regulated and how manufacturers are expected to look at the environmental impact of drugs when they are researching and making choices about which drugs to pursue. Secondly, the Minister said on veterinary medicines versus human medicines that it is there for veterinary medicines because of the impact on the terrestrial and aquatic ecosystems, the soils, et cetera. I go back to what the noble Baroness, Lady Masham, said about the impact of sewage. Human waste impacts very much on the ecosystems that the Minister acknowledged that veterinary medicines need to take into account.

Baroness Penn (Con): On the first point—considering environmental impacts in terms of research—obviously safety is one of the things primarily considered when looking at research on medicines. There is then separate provision in legislation for the safe disposal of any medicines that are not used. So we look at the safety of their use in humans and, through separate legislation, address the safe disposal of any medicines via that route.

That is also relevant to the second point on how human medicines can enter the ecosystem. I will write to the noble Baroness with further detail on that, but veterinary medicines are in a slightly different position, since we look at veterinary medicines for their impacts on animals but also have to think about their wider impact on the environment in terms of their position in the food chain. The safety standards on human medicines are much higher, because we look at their impact on patients taking them directly.

Baroness Bennett of Manor Castle (GP) [V]: I thank the Minister for her answer. I am aware this may not be entirely popular in the House, but I really feel this is an important issue the Government have not got to grips with. I am aware we have a long evening ahead of us, but none the less, I would like to test the opinion of the House.

6.32 pm

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Chadlington, L.
Chalker of Wallasey, B.
Chartres, L.
Chisholm of Owlpen, B.
Choudrey, L.
Coe, L.
Colgrain, L.
Colwyn, L.
Cormack, L.
Courtown, E.
Couttie, B.
Craig of Radley, L.
Craigavon, V.
Crathorne, L.
Crisp, L.
Cromwell, L.
Cumberlege, B.
Curry of Kirkharle, L.
Davies of Gower, L.
De Mauley, L.
Deben, L.
Deech, B.
Deighton, L.
Devon, E.
Dobbs, L.
Dodds of Duncairn, L.
Duncan of Springbank, L.
Dundee, E.
Dunlop, L.
Eaton, B.
Eccles of Moulton, B.
Eccles, V.
Erroll, E.
Evans of Bowes Park, B.
Fairfax of Cameron, L.
Fall, B.
Farmer, L.
Fellowes of West Stafford, L.
Fink, L.
Finkelstein, L.
Finn, B.
Fleet, B.
Flight, L.
Fookes, B.
Forsyth of Drumlean, L.
Fox of Buckley, B.
Framlingham, L.
Freud, L.
Fullbrook, B.
Gadhia, L.
Gardiner of Kimble, L.
Gardner of Parkes, B.
Garnier, L.
Geddes, L.
Gilbert of Panteg, L.
Glenarthur, L.
Gold, L.
Goldie, B.
Goodlad, L.
Goschen, V.
Grade of Yarmouth, L.
Greenhalgh, L.
Greenway, L.
Griffiths of Fforestfach, L.
Grimstone of Boscobel, L.
Hague of Richmond, L.
Hailsham, V.
Hamilton of Epsom, L.
Hammond of Runnymede, L.
Harris of Peckham, L.
Haselhurst, L.

Hay of Ballyore, L.
Hayward, L.
Helic, B.
Henley, L.
Herbert of South Downs, L.
Hodgson of Abinger, B.
Hodgson of Astley Abbotts, L.
Hoey, B.
Hogan-Howe, L.
Hogg, B.
Holmes of Richmond, L.
Hooper, B.
Horam, L.
Houghton of Richmond, L.
Howard of Lympne, L.
Howard of Rising, L.
Howell of Guildford, L.
Hunt of Wirral, L.
James of Blackheath, L.
Janvrin, L.
Jenkin of Kennington, B.
Johnson of Marylebone, L.
Jopling, L.
Kakkar, L.
Keen of Elie, L.
Kerr of Kinlochard, L.
Kilclooney, L.
Kirkham, L.
Kirkhope of Harrogate, L.
Laming, L.
Lamont of Lerwick, L.
Lancaster of Kimbolton, L.
Lang of Monkton, L.
Lansley, L.
Lexden, L.
Lilley, L.
Lindsay, E.
Lingfield, L.
Liverpool, E.
Livingston of Parkhead, L.
Lothian, M.
Lucas, L.
Mackay of Clashfern, L.
Mancroft, L.
Mann, L.
Manzoor, B.
Marland, L.
Marlesford, L.
Mawson, L.
McColl of Dulwich, L.
McCrea of Magherafelt and Cookstown, L.
McGregor-Smith, B.
McInnes of Kilwinning, L.
McIntosh of Pickering, B.
McLoughlin, L.
Mendoza, L.
Meyer, B.
Mobarik, B.
Mone, B.
Montrose, D.
Moore of Etchingham , L.
Morgan of Cotes, B.
Morris of Bolton, B.
Morrissey, B.
Morrow, L.
Moylan, L.
Moynihan, L.
Naseby, L.
Nash, L.
Neville-Jones, B.
Neville-Rolfe, B.
Newlove, B.
Nicholson of Winterbourne, B.
Noakes, B.
Northbrook, L.
Norton of Louth, L.
O'Loan, B.
O'Shaughnessy, L.
Pannick, L.
Parkinson of Whitley Bay , L.
Patten, L.
Pearson of Rannoch, L.
Penn, B.
Pickles, L.
Pidding, B.
Polak, L.
Popat, L.
Porter of Spalding, L.
Powell of Bayswater, L.
Price, L.
Rana, L.
Randall of Uxbridge, L.
Ranger, L.
Ravensdale, L.
Rawlings, B.
Reay, L.
Redfern, B.
Ribeiro, L.
Ridley, V.
Risby, L.
Robathan, L.
Rock, B.
Rotherwick, L.
Russell of Liverpool, L.
Saatchi, L.
Sanderson of Welton, B.
Sarfraz, L.
Sassoon, L.
Sater, B.
Scott of Bybrook, B.
Seccombe, B.
Selkirk of Douglas, L.
Shackleton of Belgravia, B.
Sharpe of Epsom, L.
Sheikh, L.
Shephard of Northwold, B.
Shields, B.
Shinkwin, L.
Shrewsbury, E.
Smith of Hindhead, L.
Smith of Kelvin, L.
Somerset, D.
Spencer of Alresford, L.
Stedman-Scott, B.
Sterling of Plaistow, L.
Stewart of Dirleton, L.
Stowell of Beeston, B.
Strathclyde, L.
Stroud, B.
Stuart of Edgbaston, B.
Sugg, B.
Suri, L.
Swinfen, L.
Taylor of Holbeach, L.
Taylor of Warwick, L.
Tebbit, L.
Thurlow, L.
Trefgarne, L.
Trevethin and Oaksey, L.
True, L.
Tugendhat, L.
Ullswater, V.
Vaizey of Didcot, L.
Vaux of Harrowden, L.
Vere of Norbiton, B.
Verma, B.
Vinson, L.
Wakeham, L.
Waldegrave of North Hill, L.
Walney, L.
Warsi, B.
Wasserman, L.
Watkins of Tavistock, B.
Wei, L.
Wharton of Yarm, L.
Whitby, L.
Willetts, L.
Williams of Trafford, B.
Wilson of Dinton, L.
Wolfson of Tredegar, L.
Wyld, B.
Young of Cookham, L.
Younger of Leckie, V.

6.43 pm

Amendments 8 and 9

Moved by ***Baroness Penn***

8: Clause 1, page 1, line 16, leave out "an attractive or" and insert "a"

Member's explanatory statement

This amendment omits the word "attractive" from Clause 1(3)(c).

9: Clause 1, page 1, line 16, leave out "conduct clinical trials or supply human medicines" and insert "—

(i) carry out research relating to human medicines,

(ii) conduct clinical trials, or

(iii) manufacture or supply human medicines."

Member's explanatory statement

This amendment clarifies the meaning of Clause 1(3)(c).

Amendments 8 and 9 agreed.

The Deputy Speaker (Lord McNicol of West Kilbride) (Lab): We now come to the group consisting of Amendment 10. 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 push this amendment to a Division must make that clear in debate.

Amendment 10

Moved by ***Baroness Sheehan***

10: Clause 1, page 1, line 17, at end insert—

"(d) the importance of prioritising the protection of human rights including citizens' right to access medicines as part of the right to the highest attainable standard of physical and mental health as stated in the International Covenant on Economic, Social and Cultural Rights of 1966;

(e) the public health safeguards within the World Trade Organization's Agreement on Trade-Related Aspects of Intellectual Property Rights which include but are not limited to the right to grant compulsory licences and the freedom to determine the grounds upon which licences are granted."

Baroness Sheehan (LD) [V]: My Lords, I rise—metaphorically—to move Amendment 10 in my name and those of the noble Baroness, Lady Bennett of Manor Castle, and the noble Lords, Lord Alton of Liverpool and Lord Crisp. It is a pleasure to have their names on an amendment to ensure that affordable medicines for all must be a consideration when regulations are made with respect to human medicines.

The price of a medicine is often determined not by the cost of production but by artificial and opaque determinants by big pharma. Egregious examples of price gouging abound. With such opportunities for eye-watering profits, the temptation to protect them is great. Big pharma has developed myriad unethical

[Baroness Sheehan]

practices to do just that. Many of these were detailed in Committee by a number of noble Lords; I do not propose to repeat them today. However, I do not want to skate over the consequences. People, even those under NHS care, suffer and/or die because of a lack of medicines that are available but not affordable.

Let me give a couple of examples. The row over the cystic fibrosis drug Orkambi went on for three years, with the NHS held to ransom, as the manufacturer Vertex refused to lower the price to an affordable one. A House of Commons debate on Orkambi was finally triggered after an online petition reached more than 100,000 signatures. A threat by the government Minister to invoke a compulsory licence, known in the UK as a Crown use licence, to allow the manufacture of the drug by a third party at a more reasonable price was all it took for Vertex to reduce its price. It is estimated that, in those three years, more than 200 people died here in the UK for lack of a drug that should have been affordable much earlier. Let us just think about that for a moment.

Just last year, we had the unacceptable behaviour of Gilead over remdesivir, then thought to be the only effective drug against Covid-19. At the height of last year's spike in cases, rationing of the drug had to be put in place in the NHS because the US had bought up all available supplies of the drug. Australia, Canada and Germany have revised their national patent laws to enable them to issue compulsory licences to respond to Covid-19 more effectively. Here, the Commons International Trade Committee made this recommendation:

> "The Government should also evaluate the case for enabling compulsory licensing of therapeutic drugs or vaccines in respect of COVID-19 to make them available as quickly, widely and cheaply as possible."

Can the Government assure us that they will invoke a Crown use licence without hesitation if necessary? I hope that the Minister can give that assurance at the Dispatch Box; we have had some conversations about this. If she does so, there will be no need for me to seek the opinion of the House.

I want to move on to the subject of non-exclusive voluntary licensing. Even though he is not at the Dispatch Box, I thank the noble Lord, Lord Bethell, for his letter in response to the questions asked in Committee. In that letter, he restated the Government's view that non-exclusive voluntary licensing is providing enough incentives to create new inventions and accelerate the development of health technologies.

However, evidence from European studies shows that over half of newly patented drugs have no added therapeutic value. Have the Government carried out any reviews into whether patents are incentivising research and development into the drugs and health technologies that the public need? For example, are pharmaceutical companies putting resources into the development of vaccines for new virus threats as they emerge, and into vaccines against existing diseases such as TB and HIV? Are they working at full throttle to develop a new generation of antibiotics that will be effective against antimicrobial resistance? I am grateful to the noble Baroness, Lady Bennett of Manor Castle, for bringing this up in her earlier speech this afternoon. However, is it these companies' job to safeguard public health? Can we rely on them to do it on our behalf? We need a review to know whether they are doing it.

If there are no plans to carry out this useful investigation, will the Minister give an assurance that she will advocate for one? That will go some way to reassuring me and other noble Lords that the Government's confidence in the existing system of patents to deliver the public health goods to safeguard us all is justified. It will also go some way towards answering those who believe that the current model works only to the advantage of unscrupulous pharmaceutical companies, whose sole raison d'être is to garner extreme profits.

To summarise, my two asks of the Government are, first, whether they will give an undertaking of their willingness to use Crown use licences and, secondly, whether they will meet me and other interested parties to explore terms for a government review into whether big pharma meets public health needs.

I would like to say a few words about the supply of vaccines for Covid-19. In his letter to me and the noble Lord, Lord Alton, the Minister, the noble Lord, Lord Bethell, stated that the Government are exploring the role of the WHO's COVID-19 Technology Access Pool, or C-TAP, to see whether it can improve access to vaccines. Please can they get a move on? Events of the past several weeks have shown us with pinpoint clarity that we are in a race against time, as new and more transmissible variants emerge.

The fact is that UK support for the Medicines Patent Pool and the eventual agreement of pharmaceutical companies to share their patents on antiretroviral drugs made the production of more affordable drugs possible. This transformed the HIV response; we need to do the same again now. We need the UK Government to support the C-TAP and get companies to share their technologies, otherwise the situation we have with shortages of vaccines in the UK will continue—not just here but everywhere, to the detriment of us all. If, however, companies refuse to share their vaccines, medicines and tests then the UK Government, and all Governments, must use their legal rights to implement the public health safeguards within the TRIPS Agreement. At the very least, that means invoking compulsory licences.

If the Government are serious about getting this vaccine to everyone in the UK and the rest of the world, they must also support the TRIPS waiver so that unhelpful intellectual property protections on Covid-19 tools can be removed. The TRIPS waiver is a proposal put recently to the WTO TRIPS council by South Africa and India, meaning that certain parts of the TRIPS Agreement should be waived for the duration of the pandemic to help us all combat its effects, because this would allow countries to collaborate in the research and manufacture of vaccines, medicines and tests to meet global demand.

With almost 2 million lives lost due to Covid-19, this is no time for restrictions in manufacturing capacity in the name of pharma profiteering. We know the power of the pharmaceutical lobby, and the influence it can bring to bear, but in this crisis human rights must take priority over intellectual property rights.

Baroness Bennett of Manor Castle (GP) [V]: My Lords, it is a great pleasure to follow the noble Baroness, Lady Sheehan, and to join the noble Lords, Lord Alton of Liverpool and Lord Crisp, in backing her important amendment. The introduction the noble Baroness provided was powerful and comprehensive, so I will not speak at length. I endorse the two asks she put to the Minister; it is important that we hear very clear, direct answers to them.

As the noble Baroness powerfully put it, there is a contest between public need and private profit, and we know that the reality of how our current system works is that private profit comes first. That means that human rights and public health trail behind. We know that so much of our healthcare system has been dragged in the direction of the disastrous US model, the most extreme example on the planet of a private, profit-driven healthcare system that has disastrous outcomes for massive costs. We also know that there are healthcare systems around the world that spend even less than we do but have a very fair and reasonable distribution of resources and money.

We often talk about these issues in moral terms; we must make sure that everyone has these medicines, and I endorse that moral approach, but in the context of the Covid-19 pandemic, nationally and globally, we must come back to the phrase, "No one is safe until everyone is safe." It is in everyone's interest that everybody in the UK and around the world has access to the best possible medicines and medical devices and that the research effort and all that wonderful power of human ingenuity are put into the best possible causes and results for public health, for the good of us all.

Lord Alton of Liverpool (CB) [V]: My Lords, I spoke at some length on this issue in Committee and am delighted that the noble Baroness, Lady Sheehan, has given us the opportunity to explore it again. She has done so with her usual thoroughness and thought. I am also pleased to follow the noble Baroness, Lady Bennett, who spoke so well. The noble Lord, Lord Bethell, has exchanged letters, as the noble Baroness, Lady Sheehan, referred to; that has been extremely helpful, as she intimated, and I think will avoid the need for a Division, but it is right we explore this issue thoroughly.

I will not repeat all the detailed arguments made in Committee, but, in headline terms, Amendment 10 is being considered in the context of exclusive intellectual property rights which can in some circumstances create monopolies, leading to high prices and supply issues for medicines and medical devices. We are seeing those issues come to the fore in the Covid-19 response.

In an Oral Question that I asked on the Floor of your Lordships' House on 30 November to the Trade Minister, the noble Lord, Lord Grimstone, I argued that in the context of hundreds of millions of Covid vaccines being held in the United Kingdom and the significant sums of public money invested in developing new drugs and treatments, notwithstanding the need to generate funds to enable future research and development, when companies such as Gilead repurpose drugs such as remdesivir and charge $2,340 for a Covid treatment that Liverpool University estimates can be done for $9, the Government should invoke their powers in such circumstances to use Crown licences to prevent patent monopolies impeding access to medicine, to ensure equitable access, prevent exploitative profiteering and recognise that affordable drugs and their fair distribution are a public good that this country should be at the forefront in providing.

7 pm

In November, the Minister the noble Lord, Lord Grimstone, responded:

> "There are existing mechanisms that facilitate the sharing of intellectual property—for example, the Medicines Patent Pool, which has been so successful with HIV. To follow up on this point, we are committed to identifying whether and how C-TAP could add value to the existing infrastructure."—[*Official Report*, 30/11/20; col. 503.]

It would be extremely helpful to me and I think to the House this evening if the noble Baroness, Lady Penn, could tell us what progress has been made in that examination of whether and how C-TAP could add value.

It is simply obscene and no better than speculative profiteering when wholly disproportionate mark-ups are added to the price of a drug. It brings to mind wartime profiteering—profits being generated while other people are making great sacrifices for the common good.

It is hugely important during this pandemic that access to medicines is a fundamental right of all, and it would be good to hear the noble Baroness's assessment of the impact that the extremely unwelcome reduction of our aid programmes from 0.7% to 0.5%—already reduced in real terms because of the fall in GNI—will have on our ability to ensure access to life-saving medicines in some of the most deprived and poorest parts of the world.

Perhaps the noble Baroness can also say what assessment has been made of the impact of the export ban, made last year on over 80 medicines to help ensure an uninterrupted supply of medicines for NHS hospitals during this public health emergency? That is highly understandable, but how has it affected access to medicines in the developing world, and are we able to increase production of some of those drugs to enable exports to be resumed? In November, the noble Lord, Lord Grimstone, promised to find out how much of the overseas aid budget has been reserved to help to pay for accessible drugs for developing countries. Perhaps the noble Baroness, Lady Penn, can tell us today.

As a young man, I got to know very well a family with three children, two of whom had cystic fibrosis. I became acutely aware of the nature of that terrible affliction. So I followed with great interest the experience of the UK trying to get access to the cystic fibrosis drug Orkambi, which was mentioned by the noble Baroness, Lady Sheehan. By issuing a compulsory licence instead of going through years of stalled negotiations with Vertex Pharmaceuticals, lives could have been saved.

Parents of children with cystic fibrosis were forced to watch their child's health deteriorate as Vertex, a US drug company, pushed for the National Health Service to pay the highest possible price for Orkambi. In response to the stalled negotiations and Vertex

[Lord Alton of Liverpool]
refusing to offer access to Orkambi on reasonable and affordable terms, Ministers stated that the UK Government would explore all options, including using a Crown use licence, to get access to the drug. The threat of a Crown use licence eventually influenced Vertex to reduce the price for Orkambi to a level that the National Health Service could afford.

That fight for the NHS to get access is just one example of the growing crisis in medicine prices globally, which using TRIPS flexibilities could help address. Over the last five years, access to drugs for the treatment of hepatitis C, breast cancer and rare diseases have all been delayed, rationed or denied to NHS patients due to price.

The ability of Governments to issue Crown use licences when patent monopolies prevent access to a medicine is a hugely important safeguard, and effectively enables a Government to issue a licence to another manufacturer to produce a generic version of a patented drug at a lower price. With medicines becoming ever more expensive, countries such as Australia, Canada and Germany have revised their national intellectual property laws to simplify the issuance of a compulsory license during a public health emergency. Is it not high time we did the same?

Baroness Walmsley (LD) [V]: My Lords, I support this amendment. When we discussed this issue in Committee, I raised the matter of Section 57A of the Patents Act 1977 and the Minister pointed out that compensation needs to be awarded to a patent holder for any loss of profits as a result of the use of a Crown use licence and argued that this should be set against the potential savings that purchasing more affordable generic alternatives enabled by a Crown use licence could bring about. Tonight, I repeat that this has never been tested in court.

The noble Baroness, Lady Sheehan, and the noble Lord, Lord Alton, mentioned Orkambi. The fact is that if the Government had issued a Crown licence and Vertex had decided to take the Government to court for compensation, the Government would probably have won the case, because they had a very strong case. Any reasonable person would have concluded that three years of failed negotiations showed that Vertex could not make the case that the NHS would definitely have bought the product from them had a Crown use licence not been issued. Had they taken the thing to court, the Government would probably have won the case, and the fact that they did not means that they really missed an opportunity to set a useful new precedent by fighting an interpretation that would render the entire Crown use provision next to useless.

I shall add just a few words about the Covid-19 pandemic. Many countries, such as Germany, Hungary, Canada and Australia, have made alterations to their patent laws to make issuing a compulsory licence easier, in the interests of public health. That is because, in those countries, it is accepted as a valuable tool that can help overcome pricing and manufacturing barriers to accessing crucial vaccines, medicines and diagnostics which could help save millions of lives. Will the UK Government follow this example, set a precedent, next time the opportunity presents itself, and make the necessary changes to our law to make it easier, not more complex, to use our legal right of issuing a Crown use licence to protect public health?

Lord Crisp (CB) [V]: My Lords, I am very pleased to add my name to the amendment in the name of the noble Baroness, Lady Sheehan. I shall be brief and limit myself to one central point, because the arguments have been put so well by noble Lords who have already spoken. At its heart, this amendment is about achieving the right balance between the public interest and private interests. In this particular context, it is clear to me that the Government should commit themselves clearly to safeguarding the public interest and to taking action on—let me stress this—those rare occasions when it will be necessary.

This is particularly vital, as other noble Lords have said today and on earlier occasions, because, sadly, there is a history of price gouging and exploitation of the public. There has also been lack of transparency and, of course, one should also note that the development of many treatments and vaccines have benefitted from public investment. I hope the Minister will be able to make the commitments that the noble Baroness, Lady Sheehan, has requested.

Baroness Jolly (LD) [V]: My Lords, the purpose of this amendment, tabled by my noble friend Lady Sheehan, with cross-party support, is to ensure that fair and affordable access to medicines for all must be a consideration when regulations are made with respect to human medicines. This is key for two reasons. The first is to ensure that medicines, including on the NHS, are available at a fair price. We know that the NHS buys medicines at an industrial scale and is very able to be tough in its bargaining to get a good deal for the taxpayer. The second is that the British Government used to play a pivotal role, through DfID, in helping many across the world in the eradication of polio and other life-changing or life-threatening diseases. Will the Minister outline what criteria are used now that DfID has been subsumed by FCDO?

On Covid-19, collaboration on the production of vaccines is critical. What is being done by the Government to collaborate in this life-saving mission? Time is of the essence. Can the Minister tell us where we are now and outline what support is going to those who have neither the contacts nor the money to fund these vaccinations? Our economy has taken a serious hit, but we have a moral duty to support those with no industry, and so no income. I endorse all the comments from the noble Lord, Lord Crisp, who has many years' experience of these issues—many more than I have. I would be grateful if the Minister could answer my questions.

Baroness Wheeler (Lab): My Lords, I too congratulate the noble Baroness, Lady Sheehan, on another important speech on this key issue and the dogged way she has pursued her arguments and key questions to the Minister. I thank her for sharing her response letter of 7 January to the Minister, which clearly sets out the issues she is still pressing the Minister to address, and I am looking forward to the response from the noble Baroness, Lady Penn, on these matters. I also welcome the very

expert and thoughtful contributions from other noble Lords both today and in Committee on this issue, drawing on their extensive professional and international experience and knowledge.

As my noble friend Lady Thornton made clear in Committee, we support this amendment. The reassurance from the Minister during Committee about the Government's commitment to collaborating with public and private partners in the UK and globally to promote affordable access to vaccines and medicines for all is welcome. Also, we are grateful for their continued commitment to the UK's obligations on the WHO TRIPS agreement and the DOHA declaration, which provide important flexibilities that support access to medicines and are especially vital during public health emergencies such as the Covid-19 pandemic that is so engulfing us today.

Noble Lords are right to underline the deep concerns of patient groups on the issue of fair and free access to medicines. I remind the House that the Royal College of Physicians, the Faculty of Pharmaceutical Medicine, the British Association of Dermatologists and other key stakeholders have called for a review of the processes for issuing sole manufacturing licences and consideration of the use of price control mechanisms in relation to costs of production to increase access to medicines at fair prices. The Government's assertion that non-exclusive voluntary licensing provides incentives for developing new medicines and health technologies is not borne out by recent evidence on newly patented drugs, as the noble Baroness, Lady Sheehan, has pointed out.

On vaccines, and our participation as a country in the global sharing and effort, access to the Covid-19 tools accelerator COVAX advance market commitment needs continuing support from the UK and wealthier nations. The promise was for matched funding if the £1 billion target was reached by the end of last year. Can the Minister update the House on this, and what will be the UK's contribution? Is there any further information on the role the UK will play in the WHO's proposed Technology Access Pool, C-TAP?

Finally, on funding of research and development, a number of noble Lords raised the issue of the absence of analysis of, and data on, how much public and private money goes into the development of new vaccines and medicines. The Minister referred to the VPAS voluntary pricing scheme negotiated with the industry, which runs alongside the statutory pricing scheme, the NICE appraisal process and the commercial NHSI arrangements. The scheme is designed to support patient access to innovative medicines and expires next year, so these coming months will provide a crucial opportunity to commence a detailed review on how the research and development of medicines are actually funded. This would not only strengthen the Government's negotiating position but lead to greater transparency in the UK's future relationship with the pharmaceutical industry, which we all want to see.

Baroness Penn (Con): My Lords, first, I would like to address the issue of patient and clinician access to affordable medicines in the UK. Patient and clinician access to affordable medicines is at the core of the NHS and this country's healthcare policy. This Bill will not diminish that. Indeed, a safe and innovative regulatory regime for medicines and devices will support that outcome, although patient access is not dealt with directly in this Bill. The Government have recourse to a number of mechanisms to ensure that patient and clinician access to affordable medicines is upheld. For example, the price of branded medicines is controlled by the 2019 voluntary scheme for branded medicines pricing and access. The National Institute for Health and Care Excellence also continues to ensure cost-effectiveness for medicines purchased by the NHS.

As the noble Baroness, Lady Sheehan, has noted, in line with the flexibilities in the TRIPS agreement, the Government also retain the right to order Crown use of patented medicines under Section 55(1)(a) of the Patents Act, where collaborative approaches are not successful or we determine that it is in the public interest. I should emphasise that this would be used only in very narrow circumstances, such as an emergency. The UK has an internationally renowned IP system, which cultivates an innovative pharmaceutical sector, attracts generics manufacturers, and ensures that the NHS has access to the most cost-effective options. We will continue to work with these stakeholders to provide cost-effective access to Covid-19 therapies and vaccines, in the UK and globally, on a voluntary basis.

7.15 pm

I will answer the two questions put by the noble Baroness, Lady Sheehan, directly. On the question of Crown licences, if the Government deemed it necessary, we would make use of compulsory licensing or Crown use provisions, but we have made it clear to interested partners that we do not believe this is required at this point in time. The second question put by the noble Baroness was on whether the Government had carried out any review into the efficacy of the patent system to incentivise research and development into vaccines, therapeutics and health technologies. In 2011 a review by Professor Ian Hargreaves into the UK's IP system was commissioned, to look at whether it was sufficiently well designed to promote innovation and economic growth. The review found that

"the UK's patent system has played a well understood role in supporting innovation"

across the economy, including in pharmaceuticals, and plays an important role in incentivising investment in research and development. However, I acknowledge that some time has passed since that review was undertaken. There have been other specific issues raised by the noble Baroness and other noble Lords in this debate, and I would be happy to meet with interested parties to discuss those issues further.

I will now address the concerns raised by noble Lords about access to medicines and vaccines globally. The Government are committed to improving equitable access to essential medicines for people in low-income and middle-income countries. That is why the UK is the largest donor to Gavi, the vaccine alliance, having supported it since its inception in 2000. In the context of the Covid-19 pandemic, the Government recognise that the world urgently needs access to safe, effective, quality and affordable vaccines, diagnostics, medicines and other health technologies. As part of this, we remain committed to the arrangements in the TRIPS agreement, including the public health safeguards that it provides for signatory countries.

[Baroness Penn]

The existing IP framework supports research and development for new medicines and technologies, while voluntary licensing mechanisms and other flexibilities, as noted by the noble Baroness, ensure the transfer of and access to technology and know-how. Indeed, a strong IP framework was integral to the rapid development of safe, clinically effective vaccines.

The Government continue to think that the fastest way to deliver vaccines across the globe is to fund efforts such as the COVAX facility and the access to Covid-19 tools accelerator. To that end, we have committed up to £548 million to COVAX, which is one of the largest contributions made by any country. This will enable developing countries to access vital vaccines against Covid-19.

The noble Lord, Lord Alton, and the noble Baroness, Lady Wheeler, asked for an update on C-TAP. The Government continue to discuss C-TAP with stakeholders to identify where they can contribute to this initiative for global benefit. We recognise the need to understand how industry and research institutions can assist this initiative and we are currently working with the WHO to facilitate this.

Further, the existing flexibilities in the international IP framework and opportunities for voluntary arrangements are already being used to support the global response to Covid-19. For example, AstraZeneca has reached a licensing and technology transfer agreement with the Serum Institute of India to supply 1 billion doses of its vaccine to low-income and middle-income countries. Another initiative, DiaTropix, brings together British and Senegalese partners to share technology to produce 10 million Covid-19 antibody tests by March 2021, for use across west Africa.

I hope that this reassures noble Lords that the Government are prioritising access to medicines, vaccines and therapeutics in the UK and internationally, including for the poorest and most vulnerable. On that basis, I hope that the noble Baroness, Lady Sheehan, is able to withdraw her amendment.

Baroness Sheehan (LD) [V]: My Lords, this has been a stimulating debate and I sincerely thank all noble Lords and noble Baronesses who have taken part. That very much includes the Minister, who responded with her customary courtesy and thoughtfulness.

I thank the noble Baroness, Lady Bennett of Manor Castle. As ever, she brought up the issue of human rights and how they must not be trumped by intellectual property rights—sentiments I agree with 100%.

I thank the noble Lords, Lord Alton of Liverpool and Lord Crisp, who raised a question central to the whole issue of intellectual property rights: who actually pays for the investment in drug development? This is shrouded in secrecy and we must try to shed some light on it. I hope that we can explore that in discussion when we have the meeting the Minister has very kindly agreed to. Drug development is done not just by private companies; taxpayer-funded research and R&D institutions play a huge part, as do philanthropic organisations and NGOs.

I am very grateful to my noble friend Lady Walmsley for raising Section 57A, which the noble Lord, Lord Bethell, brought up as a defence against using compulsory licensing. It is a moot point, as my noble friend said. I think that the argument the Government used would in fact nullify the whole concept of Crown use.

I thank my noble friend Lady Jolly for the focus she placed on the major challenges developing countries face, even more so now that DfID no longer exists and 0.7% has been reduced to 0.5%.

I thank the noble Baroness, Lady Wheeler, for her words. She was absolutely right to draw attention to the collated briefing of the Royal College of Physicians and its partners in highlighting prices in the NHS for both generic medicines and those that enjoy patent rights.

I thank the Minister, and I will take her up on her offer of a meeting in due course. I beg leave to withdraw the amendment.

Amendment 10 withdrawn.

Amendment 11

Moved by ***Baroness Penn***

11: Clause 1, page 1, line 17, at end insert—

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

Amendment 12 (to Amendment 11) not moved.

Amendment 11 agreed.

The Deputy Speaker (Lord Bates) (Con): We now come to the group consisting of Amendment 13. 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 it clear in the course of the debate.

Clause 2: Manufacture, marketing and supply

Amendment 13

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

13: Clause 2, page 2, line 32, at end insert ", or

(o) the use of tissues or cells (within the meanings given by regulation 5(1) of the Human Tissue (Quality and Safety for Human Application) Regulations 2007 (S.I. 2007/1523)) in relation to human medicines."

Member's explanatory statement

This amendment would enable regulations under Clause 1(1) to make provision about the use of human tissues or cells in relation to human medicines.

Lord Hunt of Kings Heath (Lab) [V]: My Lords, I am delighted to move my amendment, which follows constructive and very helpful discussions with the Government. I am particularly grateful to the noble Lords, Lord Bethell and Lord Ahmad, the noble Baroness, Lady Penn, and their officials for their help, and to my fellow sponsors, the noble Baronesses, Lady Finlay

and Lady Northover, and the noble Lords, Lord Ribeiro and Lord Alton, for the huge support they have given. I should also mention the enormous help I have had from Victoria Ledwidge of the end transplant abuse in China campaign.

The world is increasingly aware of China's forced organ harvesting from prisoners of conscience. This horrific crime of forcibly removing the organs from living victims—a process leading to inevitable murder—has recently been found by the China Tribunal to be happening extensively.

Millions of Chinese citizens are currently detained in labour camps. UN experts estimate that at least 1 million Uighurs are being held in camps in the region of Xinjiang. Elsewhere throughout China, other ethnic and religious minorities are also being held in labour camps, such as Tibetan Buddhists, Falun Gong practitioners and Christians. This modern-day slavery has been entering the UK supply chain, and there is no doubt that we are currently complicit. I must say that I welcomed the Statement made today by the Foreign Secretary.

Last year, the China Tribunal concluded:

"Forced organ harvesting has been committed for years throughout China on a significant scale and that Falun Gong practitioners have been one – and probably the main – source of organ supply"

and that:

"In regard to the Uyghurs the Tribunal had evidence of medical testing on a scale that could allow them, amongst other uses, to become an 'organ bank'."

I hope the Government will seek to put pressure on the World Health Organization to take this seriously.

Domestically, the Bill provides an opportunity to prevent British complicity in such crimes and to send an important message to other countries. My amendment is designed to deal with gaps in current UK human tissue legislation. Currently, the Human Tissue Act does not require appropriate consent for imported human tissue. In addition, imported human tissue for use in medical research does not require traceability. Currently, neither the Human Tissue (Quality and Safety for Human Application) Regulations nor the Human Tissue Act require appropriate consent for imported human tissues for use in medicines. My amendment gives powers to Ministers to put this right. I should explain that the words "tissues" and "cells" are terminology which encompass all the human material that is used for the purposes of medicines. This includes organs.

The amendment would not include the prohibition of the dreadful travelling circus of Real Bodies exhibitions, nor would it include medical equipment manufactured and exported from the UK for the purpose of extracting or preserving human organs if exported to China. The noble Lord, Lord Alton, will come back to that point, and I know he has had some very helpful discussions with the noble Baroness, Lady Penn.

None the less, the passing of my amendment would be a significant action. By giving Ministers the power to make regulations, this is a specific act by the UK in relation to the abhorrent practices in China that I have spoken of. Of course, we need to see those regulations introduced and passed through Parliament. But, internationally, the UK's action will be seen as a marker and a real signal to other countries.

Baroness Finlay of Llandaff (CB) [V]: My Lords, it is a great pleasure to follow the noble Lord, Lord Hunt of Kings Heath, on this very important amendment. It is an example of how, with high moral standards, the Ministers involved have been listening. With others, I wish to sincerely thank the noble Lords, Lord Bethell and Lord Ahmad of Wimbledon, and the noble Baroness, Lady Penn, who have listened to very difficult information and accepted the important responsibility we have on the world stage.

7.30 pm

Many of us have been concerned for some time about forced organ harvesting from prisoners of conscience. The amendment is a strong signal that the UK does not turn a blind eye, however uncomfortable facing the problem may be.

Of course, there are other aspects beyond the scope of the Bill that we cannot ignore. First, the amendment covers only medicines. I have an ongoing concern that medical instruments or machines could be developed by experimenting on prisoners through practice operations or procedures. We must never forget the history of Dr Mengele and his colleagues, who claimed scientific pursuit, inflicting fatal torture on innocent people interned in concentration camps. Can the Government confirm that they will be increasingly vigilant over how imported products have been developed and manufactured, and make sure that we do not export anything that can continue some of the atrocities that we have heard of?

Secondly, there is a gap in the HTA regulations around proof of consent over imported tissues. Will the Government address that gap and ensure that newly obtained tissues cannot be imported without proper consent to donate those tissues?

Lastly, will the Government undertake to continue to support efforts to tackle transplant tourism? We know, sadly, that some people have misguidedly gone to China for organ transplantation. Tackling this requires a concerted effort, including increasing donor rates in other countries, as well as here, so as to decrease the demand that fuels killing for organs. But change takes time.

Today, we welcome wholeheartedly what the Government have done and the very important signals that are now being sent to the rest of the world. Like other noble Lords, I thank all those involved most sincerely.

Baroness Northover (LD) [V]: My Lords, praise will be ringing in Ministers' ears from the first group of amendments, concerning the patient commissioner, in the name of the noble Baroness, Lady Cumberlege. There is praise again for listening on this issue.

The noble Baroness, Lady Penn, had the task, in the first instance, of rebutting the original amendment. I, for one, asked her to read the China Tribunal report to get a strong sense of the horrendous problem that was part of the context for this amendment. You could see that she was listening, and subsequent engagement has been very useful, as the noble Baroness, Lady Finlay and the noble Lord, Lord Hunt, have said. I am glad that the ministerial team has responded. It comes

[Baroness Northover]
on the day that the Foreign Secretary has made a Statement in the Commons that focuses on human violations against the Uighurs.

I pay tribute to the noble Lord, Lord Hunt, for consistently, and with great political skill, taking forward this issue, as he has done on the scandal of the "Real Bodies" exhibitions. I also pay tribute to the others who have worked in this area, including the noble Baroness, Lady Finlay, and the noble Lords, Lord Ribeiro and Lord Alton. This is a terrible problem and one that it would be easy to turn away from, but those noble Lords simply do not do so.

We need to make further progress across this area, and I am sure this will be taken forward. Forced organ harvesting, which according to the China Tribunal has happened on a mass scale in China, is a horrific crime. Organs are removed from living victims by doctors in state-run hospitals for transplantation, inevitably killing the victim in the process.

As the noble Lord, Lord Hunt, said, the China Tribunal concluded that many victims were Falun Gong practitioners. A brutal and systematic crackdown on Falun Gong was initiated in 1999, with the Chinese leadership ordering their eradication. Many disappeared without trace, which was when China's organ transplant trade rapidly increased. As we now recognise, in recent years there has been a similar crackdown on the ethnic-minority Uighurs. They have been put into re-education camps and have endured forced labour, brainwashing, rape and torture. The China Tribunal stated:

"In regard to the Uyghurs, the Tribunal had evidence of medical testing on a scale that could allow them, amongst other uses, to become an 'organ bank'."

Our amendment aims to ensure that no human tissue or cells that have been sourced from victims of organ harvesting can be used in human medicines or enter the UK medical supply chain. This is the first time the United Kingdom Government will enact legislation in this area, and we must hope that it sends a strong and clear message internationally. Thus far, as the noble Lord, Lord Hunt, said, it is enabling, but the Government will know that many will be monitoring this area. We need to see those regulations in place.

I note the weakness of the HTA assessment of the "Real Bodies" exhibition, on which I am sure the noble Lord, Lord Alton, will expand, and its acceptance of what it was told, seemingly at face value. The noble Baroness, Lady Finlay, also, rightly, pointed to this. The amendment that we are agreeing today will help move things forward. I am grateful to the Government and their lawyers for working on this, although, clearly, we will all need to be vigilant and there is still much to do.

Lord Ribeiro (Con) [V]: My Lords, like the noble Lords who have spoken before me, I thank the Minister and the Government for accepting our amendment. I believe it sends a powerful message, not only to China but to other countries such as Pakistan and India, to which I referred in my speech of 28 October in Committee. In discussion with the Foreign Office, through the noble Lord, Lord Ahmad, we were reassured that the diplomatic strategy would be to continue lobbying as many countries as possible on the issue of human rights and the immoral practice of forced organ harvesting. With the noble Baroness, Lady Finlay, we undertook to raise awareness with the British Medical Association and the surgical royal colleges.

It is worth noting the World Health Organization's *Guiding Principles on Human Cell, Tissue and Organ Transplantation*. Any programme such as the kidney pairing exchange, which makes it possible to utilise kidneys that are biologically incompatible between patients and their genetically or emotionally related donors, must follow and respect the WHO's *Guiding Principles* of practice, particularly principles 3 and 5, which are worth quoting.

Principle 3 says:

"Live donations are acceptable when the donor's informed and voluntary consent is obtained, when professional care of donors is ensured and follow-up is well organized, and when selection criteria for donors are scrupulously applied and monitored. Live donors should be informed of the probable risks, benefits and consequences of donation in a complete and understandable fashion; they should be legally competent and capable of weighing the information; and they should be acting willingly, free of any undue influence or coercion."

Principle 5 states:

"Cells, tissues and organs should only be donated freely, without any monetary payment or other reward of monetary value. Purchasing, or offering to purchase, cells, tissues or organs for transplantation, or their sale by living persons or by the next of kin for deceased persons, should be banned."

In 2017, the World Health Assembly supported a concept of financial neutrality to protect vulnerable people from being exploited. That is the essence of what this amendment achieves, and I am grateful to the Government and to the noble Lord, Lord Bethell, and the noble Baroness, Lady Penn, for endorsing it. I hope that they will maintain their pressure on the WHO to end these practices.

Lord Alton of Liverpool (CB) [V]: My Lords, I start, as others have done, by thanking the noble Baroness, Lady Penn, and the noble Lord, Lord Bethell, for the way in which they have engaged with noble Lords such as the noble Lord, Lord Hunt, who has put so much work into this—along with the noble Baronesses, Lady Finlay and Lady Northover, and the noble Lord, Lord Ribeiro—in trying to draw our attention to the enormity of the depredations that have occurred in China through forced organ harvesting. It is very productive that, this evening, the Government have been able to come forward with an amendment that has been agreed with the sponsors of the Committee amendment, having listened to the argument. I am especially grateful, as others have been, to the noble Baroness, Lady Penn, for the way in which she has engaged.

I will come back in a few moments, if I may, to two other issues that I have raised with her but which are not included in this amendment. They concern consent and the equipment that could be used in the extraction, freezing and harvesting of organs in China, and the question of whether, if British companies were involved in the production of such equipment, there is anything that we could do to forestall that.

On consent, the noble Baroness, Lady Northover, mentioned that, thanks to the noble Baroness, Lady Penn, we have now seen the reports of the Human

Tissue Authority of 2018 following its visit to the National Exhibition Centre in Birmingham to examine the plastinated bodies that had been taken there. These were corpses that had been put on public display—what the noble Lord, Lord Hunt, referred to as part of a sort of travelling circus. A second exhibition was held later in the year.

It was extraordinarily naïve—at best—that no more probing was done into the origins of those bodies or how consent could possibly have been given from unknown, anonymised sources. Of course, it leaves the question hanging in the air of whether these were people who had been executed—they probably had been. Sadly, we know that that is the fate of many people, whether they are Falun Gong practitioners or people from different denominational minorities or faith communities, including the Uighurs. We have heard much already this evening, as well as in the Statement from the Foreign Secretary, Dominic Raab, in the House of Commons this afternoon, about the plight of 1 million people who have been incarcerated because they will not conform to the diktats of the Chinese Communist Party.

It is extraordinary that such things can happen in the 21st century, but they are happening. That is why we have to be vigilant and do what we can to prevent the exploitation of people who are caught up in these circumstances. I think particularly this evening of a young woman called Zhang Zhan, who was arrested as a citizen journalist. She is a lawyer by background and had gone to Wuhan to investigate the origins of the coronavirus. She has been languishing in a jail ever since, for some of the time on hunger strike. We know that many dissidents—people who have spoken out against the regime—including lawyers, have been arrested, and some have disappeared, never to be seen again.

Therefore, it is crucial that we discover the origins of the bodies that are used in these sorts of exhibitions and displays, which I personally believe should be prohibited in their entirety. The idea that they can be paraded for macabre purposes should fill people with a sense of disgust. The anonymity of the cadavers should have made the Human Tissue Authority see that this was an issue that it should not just have turned a blind eye to. It is not good enough simply to say that we have a strong regulatory authority. We do: we have strong regulations, many of which came out following the scandal at Alder Hey in Liverpool. However, since then, we have failed to plug the loophole that I and others identified in 2018. We used that phrase—a loophole—in a letter to the *Times*, but it also appeared in an article in the *Lancet*. There was a loophole that needed to be filled when it came to organs and tissues from outside the United Kingdom.

The amendment goes some way to addressing that but I think that there also needs to be further regulation on the issue of consent. I also feel—and I would like to press the Minister on this—that we must do more about the export of equipment from the United Kingdom that could be used in forced organ harvesting. Maybe this could be done through export licence control. I noticed in the Statement to the House of Commons this afternoon and in the letter that has been circulated to Peers this evening by the right honourable Dominic Raab, the Foreign Secretary, that he talks about there being a review of export controls as they apply to the situation in Xinjiang. He says that these measures are among the most stringent being implemented globally to help ensure that supply chains are free from forced labour.

That is welcome, but how ironic it would be if, in stopping coming into this country things that have been manufactured by slave labour in Xinjiang, we permitted the export of things to Xinjiang and elsewhere in China that were being used in the extraction, freezing and transportation of body parts in order to enable China to promote one of the biggest organ industries in the world. The noble Baroness, Lady Finlay, was right to say that we also need to do far more about the phenomenon of people travelling to other parts of the world to take organs from others. That kind of organ tourism is something that the British Government need to do more about.

That is all that I want to say. I look forward to hearing the reply from the noble Baroness, Lady Penn.

7.45 pm

Baroness Jolly (LD) [V]: My Lords, this has been a detailed, depressing debate and I feel completely powerless. I pay tribute to the noble Lord, Lord Hunt of Kings Heath, for his phenomenal tenacity on this and to the noble Lord, Lord Alton, for his tireless work. I am sure others do just as much and I do not know about it.

Amendment 13, led by the noble Lord, Lord Hunt, and signed by my noble friend Lady Northover and the Minister, would enable regulations under Clause 1(1) to make provision about the use of human tissues or cells in relation to human medicines. The amendment pushes the Government to respond to the horrifying practice of forced organ harvesting that evidence suggests is taking place in China. The account of organ banks by the noble Baroness, Lady Finlay of Llandaff, was chilling. Liberal Democrats, among others, have been vocal about the appalling human rights violations faced by the Uighurs. The amendment would be an important step in the right direction, and we urge the Government to do all they can to put an end to this practice.

It is most unusual for a Minister on a Bill to be included as a signatory to an amendment. It should send a real signal that our Government do not support this appalling treatment of minorities, and I commend him on this stance. I would be grateful if the Minister, in summing up, could tell us whether there is anything we could practically do on this matter.

Lord Collins of Highbury (Lab): My Lords, I too thank all noble Lords who put their names to this amendment. It truly reflects the cross-party concern on this issue. I pay particular thanks to my noble friend Lord Hunt and the noble Lord, Lord Alton, who have been absolutely persistent in raising this at every level. We have debated this not only on this Bill but in other debates in this House.

I thank the noble Lord the Minister and particularly the noble Baroness, Lady Penn, for the regular meetings she has had with noble Lords to listen to our concerns. The fact that they have both listened and acted is a

[Lord Collins of Highbury]
reflection of the good work this House can do in not acting in a partisan way. We have put the issue first and delivered on it. I am also grateful to the noble Baroness for the way she has gone to the limit of this Bill's scope. I recognise that the Bill's scope has placed limitations on us, but it does not stop us speaking about and delivering on the political issue that my noble friend and the noble Lord, Lord Alton, have raised. I am particularly pleased to thank everyone concerned.

I will pick up a couple of points. One of the big political issues that started my noble friend's concern was the exhibitions we saw. The idea that consent could be given by dead or dying prisoners in China is absolutely ridiculous. We should never accept it and should continue to ensure that we strengthen regulation in that regard. It will be ongoing work.

I also pick up a point that both my noble friend Lord Hunt and the noble Lord, Lord Alton, raised in Committee; in fact, we raised it at Second Reading. We named two companies involved in supplying organ-preserving devices to mainland China. This could explain how organs are being transported around China, supporting this obnoxious practice of harvesting organs.

I was pleased to read the statement made by Dominic Raab in his announcement that the Government will conduct an urgent review of export controls, specifically as they apply to the situation in the Xinjiang Province, to, as he said,

"make sure that we are doing everything that we can to prevent the export of any goods that could directly or indirectly contribute to human rights violations in that region."

We have heard in our debates in this House that that is potentially going on, and I hope that the Minister will be able to respond that she will work with both the FCDO and the International Trade Department to ensure that the concerns raised today will be reflected the review that Dominic Raab has promised. I hope she will take that up and, as raised by both the noble Baroness, Lady Northover and my noble friend Lord Hunt, the China tribunal's conclusions about the nature of the practice that has been going on and the fact that the Uighurs and Falun Gong practitioners are its main victims.

As we have said in many debates, the Communist Party of China and the Government of the People's Republic have denied all claims about this, despite the evidence of the tribunal, and have relied on the WHO clearing them of wrongdoing. Of course, we know that that is because the WHO does not have an independent expert compliance assessment mechanism: it relies on the Government of China and the Chinese Communist Party simply saying that it does not happen. I know that the noble Lord, Lord Ahmad, has been consistent and persistent in raising this issue and it has been raised with the WHO, but I hope the Minister will be able to respond today that we will continue to raise it through the organ of the WHO.

In conclusion, I repeat what has been said by all noble Lords. The importance of this amendment is not simply the specific points of law that it will address. The most important thing the amendment and this debate tonight does is send a very clear message that we will not tolerate such appalling acts against humanity and will deliver for the people of China, not for the Communist Party of China.

Baroness Penn (Con): My Lords, I begin by thanking all noble Lords for their valuable and ongoing engagement on the matters raised by Amendment 13. Throughout the Bill's passage, we have heard numerous passionate and heartfelt speeches on the allegations of organ harvesting in China and how the UK seeks to guard against complicity in any such practices. Anyone listening to speeches made by noble Lords in Grand Committee or this debate cannot have failed to understand the considerable strength of feeling behind those concerns. My noble friend Lord Bethell and I have greatly welcomed the thoughtful and constructive discussions on these issues.

Earlier today, the Foreign Secretary made an announcement setting out an ambitious package of measures that will help to ensure that no British organisations, whether public or private, are contributing inadvertently to human rights violations in Xinjiang. This demonstrates that we will not stand by as violations there continue. We will never hesitate to stand up for human rights as a force for good in the world.

The Government's position is clear: if true, the practice of systemic, state-sponsored organ harvesting would constitute a serious violation of human rights. The China Tribunal report has been carefully considered by the FCDO and adds to a growing body of evidence about the disturbing situation that Falun Gong practitioners, Uighurs and other minorities face in China.

Given the considerable interest in these and related concerns over human rights violations in China, my noble friend Lord Ahmad, Minister for South Asia and the Commonwealth, has met repeatedly a number of noble Lords with particular interest in these matters over recent months. I trust that these discussions have provided some assurance of the Government's absolute commitment to strong UK action. The Minister, is, I know, committed to ongoing engagement in coming weeks.

During Grand Committee, the noble Lords, Lord Hunt and Lord Alton, made clear their view that the WHO should be further engaged to take more robust action and to provide greater transparency on organ transplant practices in China. I am pleased to tell noble Lords that continued efforts by FCDO Ministers to engage the WHO on these matters have led to a valuable meeting between senior officials at the UK Mission in Geneva and Jane Ellison, executive director for external relations at the WHO. These discussions have opened up dialogue with key international partners on organ harvesting allegations, which we are committed to continuing.

Crucially, noble Lords may know that my noble friend Lord Ahmad has committed to meeting Sir Geoffrey Nice QC in the coming months to discuss further the findings of his report. The FCDO is, I know, absolutely committed to considering carefully all and any evidence presented on allegations of organ harvesting in China. I want to take the opportunity on behalf of the Minister for South Asia and the Commonwealth to

thank my noble friend Lord Ribeiro and the noble Baroness, Lady Northover, for their role in engaging international medical organisations on these matters.

I now turn to the specifics of the amendment tabled in the name of the noble Lord, Lord Hunt, to which I am pleased that my noble friend Lord Bethell has put his name. The amendment provides absolute clarity that the powers in Clause 2 of the Bill can be used to make regulatory changes about the use of human tissues or cells in legislation relating to human medicines.

While it is important to be absolutely clear that the use of imported tissue in any medicines on the UK market is extremely limited—there is only one licensed medicinal product in the UK that uses donor-derived tissues, and that tissue is sourced from within the EU—we are all in agreement that we would not want the UK medicines industry compromised by the use of human tissue or cells sourced through human rights violations. The amendment will ensure that we have the power to take action to amend or supplement provisions governing the use of human tissues in medicinal products in the Human Medicines Regulations 2012 or the Medicines for Human Use (Clinical Trials) Regulations 2004 to help assure the integrity of tissues and cells used in UK medicines if necessary.

The drafting, an iteration of the wording of a similar amendment tabled by the noble Lord, Lord Hunt, in Grand Committee, delivers important clarity on a number of points. In particular, the specific reference to both tissues and cells provides certainty on the scope of materials captured. The reference to definitions of those terms under the Human Tissues (Quality and Safety for Human Application) Regulations 2007 ensures consistency with wider UK legislation.

I am also assured that this drafting allows for provisions to encapsulate the full stream of activities in the regulation of medicines that could relate to the use of tissues and cells. Of course, as with any such provisions brought forward under Clause 1 of the Bill, this would be informed by public consultation, a critical step in ensuring the full consideration of an appropriate approach and mitigating against any unintended consequences—for instance, for the supply or development of medicines in the UK.

Finally, I recognise that noble Lords have raised a number of other important, related questions on how we safeguard domestic practices from being at risk of compromise by human rights violations overseas. In these discussions, we have sought to be completely clear with noble Lords on the limitations of what can be done under this Bill. However, let me reassure noble Lords that concerns have not gone unheard.

First and foremost, on the consent standards applied to tissues imported for the purposes of public display, I am pleased to announce that we will take forward work to strengthen the Human Tissue Authority's code of practice on public display for imported tissues. Although such imports are rare, we are committed to ensuring that when tissues are imported from outside the UK for the purposes of display, the consent standards applied are clear, firm and enforceable.

8 pm

By strengthening key safeguards, we can ensure that robust assurances on consent are fully received, considered, assessed and recorded, before any display licences are issued to importers or exhibitors. We will also look at how the Human Tissue Authority's underpinning licensing processes can be used to strengthen compliance with standards. We will also be proactive and robust in communicating best practice to establishments and importers, for instance by issuing clear, detailed guidance on consent requirements to any establishments considering undertaking public display. This work is under way, and I am confident that, as a result, we can ensure that no exhibitors can display imported bodies without robust evidence of consent.

A related question was raised by the noble Lord, Lord Alton, and other noble Lords, concerning whether the export of medicines and medical devices could ultimately be used for unethical purposes. In the context of the UK export of medicines and devices, I must first emphasise the UK's critical role as a leading supplier of medicines, vaccines and other essential health commodities which bring enormous benefits in low and middle-income countries around the world. Any proposal to apply rigorous export controls to medicines and devices presents a significant risk of unintended consequences for the many individuals who receive often life-saving safe and effective products supplied by UK companies. This risk is particularly pertinent when considering the types of medicines and devices that could theoretically be used for the purposes of organ extraction. This could capture any device used in general surgery, from syringes, sutures, scalpels up to ventilators and bypass machines. For medicines, it would include anaesthetics, muscle relaxants and antibiotics. Such steps could unduly affect the export of a huge range of goods being used for legitimate and critical functions.

Of course, it is absolutely right that we guard against the UK—and UK companies—being complicit in human rights abuses. The Government strongly back the business and human rights agenda and have consistently supported the United Nations *Guiding Principles on Business and Human Rights* as the authoritative voluntary international framework to steer practical action by Governments and businesses worldwide. We are clear that we expect all our businesses to comply with all applicable laws, identify and prevent human rights risks and behave in line with the guiding principles. As demonstrated by the Foreign Secretary's announcement earlier today, we are prepared to go further where there is clear cause for concern that UK actors could inadvertently contribute to human rights abuses overseas. I assure the noble Lord, Lord Collins, that I will convey to the FCDO, as part of that work, the concerns raised throughout the debate on this Bill and the issues that we have discussed at all stages.

Again, I thank noble Lords for their valuable and constructive engagement on these issues, and trust that they will be reassured by the announcement made earlier today by the Foreign Secretary to help ensure that no British organisations are contributing inadvertently to human rights violations in Xinjiang. I welcome Amendment 13, tabled by the noble Lord, Lord Hunt, and I am pleased to support it.

Lord Hunt of Kings Heath (Lab) [V]: My Lords, this has been a short but incredibly important debate. In addition to the noble Lords that I have already thanked, I pay tribute to the noble Baroness, Lady Jolly, and my noble friend Lord Collins, for their sterling support throughout the passage of this Bill. It is much appreciated.

I stress that this amendment is not the definitive response to the horrific abuse taking place in China. It is enabling legislation, and there is much to do, as the noble Baroness, Lady Finlay, said. We need greater vigilance over exports. Transplant tourism is another area of real concern.

The noble Baroness, Lady Northover, and the noble Lord, Lord Alton, spoke about the HTA and its rather relaxed approach to the "Real Bodies" exhibitions. I find it extremely embarrassing that one of these exhibitions took place in Birmingham, but I am glad that the Commonwealth Games are coming to the city next year and that it has adopted a robust ethical policy which, if extended to the National Exhibition Centre in the future, would ensure that we would not see these exhibitions again.

The noble Lord, Lord Alton, has identified a number of other areas, to which the Minister responded to today, and the noble Lord, Lord Ribeiro, spoke very forcefully about the role of the World Health Organization. Again, I am very glad that the Government and the FCO in particular are talking closely to the WHO about it.

The noble Baroness, Lady Penn, sent a number of very important messages at the end: the revision and toughening up of the HTA's code of practice and licensing procedures; and she talked about exports of medicines and devices. These are all welcome. However, we cannot be complacent. As my noble friend Lord Collins says, we cannot as a country show any tolerance towards these barbaric acts. This amendment is significant, particularly because it shows that the UK, with the support of government Ministers, is taking it seriously, and I am very grateful to all noble Lords who have helped to make this happen.

Amendment 13 agreed.

The Deputy Speaker (Lord Alderdice) (LD): We now come to the group consisting of Amendment 14. 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 the debate.

Clause 3: Falsified medicines

Amendment 14

Moved by ***Lord Clement-Jones***

14: Clause 3, page 3, line 4, leave out "for any purpose to do with human medicines" and insert "for the purpose of ensuring patient safety"

Member's explanatory statement

This amendment would narrow the use of data in relation to falsified medicines to that which ensures patient safety.

Lord Clement-Jones (LD) [V]: My Lords, on 4 November in Grand Committee, the noble Baroness, Lady Thornton, and my noble friend Lady Jolly introduced amendments designed to limit the ambit of the information-gathering powers under Clause 3, which deals with falsified medicines. I raised the subject at Second Reading but was unable to be present for the debate in Grand Committee.

The Minister, the noble Lord, Lord Bethell, said in resisting the amendments:

"We also want to explore creative uses of information as long as they are for public interest purposes. Therefore, we do not want to constrain or limit options ahead of engagement with stakeholders."

It was not at all clear what the Minister meant by "exploring creative uses of information", and in fact it was quite concerning given that these have not been set out anywhere in any consultation document. However, he went on to say:

"I should make it very clear that the overarching principles of the Bill as set out in Clause 1 also apply to our powers here. The scope of the purposes mentioned is not unfettered. The appropriate authority must be satisfied that regulations dealing with anything under Clause 3—not just around how the information will be used—will promote the health and safety of the public. In making that assessment, the appropriate authority is required to have regard to the three considerations discussed previously in Committee."—[*Official Report*, 4/11/20; col. GC 326.]

Of course, as the result of the very welcome government Amendment 4, the safeguarding of public health is the key objective, and by Amendment 6, Clause 1(3) has been tightened up too. However, having carefully considered these amendments and the Minister's previous response, I must still question his interpretation of Clause 3 and how it interacts with Clause 1. Clause 3(1)(b) currently says that the regulations may make provision about

"the use, retention and disclosure, for any purpose to do with human medicines, of information collected for the purpose of preventing the supply of falsified human medicines."

At best there is a conflict between the two clauses, and at worst Clause 3 is open-ended and gives the Government far too much discretion in the scope of regulations under Clause 3.

In the discussions we have had with the Minister between Committee and Report—for which I am grateful—it became clearer that we need to ensure that this information regarding falsified medicines is used for limited purposes. The Minister cited a whole range of possible uses for the data, which came as a considerable surprise. As I said earlier, there has been no industry consultation, despite considerable ambition on the department's behalf. That is why in this amendment we have tied the purpose to "ensuring patient safety". What possible objection could there be to this limitation? Why would the Government want any wider scope, especially if the Minister believes that Clause 1 already provides a limitation?

I have now seen the brief announcement issued by the department on the consultation on the regulations to be carried out on a new national scheme. It says:

"We are committed to public consultation around the need and details of any national scheme, as well as a specific consultation on the use of data collected as part of any scheme."

That lacks detail, to say the least.

Many noble Lords have been briefed by the Company Chemists' Association about the commercial sensitivity of this data. As my noble friend Lady Jolly said in Grand Committee:

"The Department of Health and Social Care already has access to a very wide range of data on the sales of medicines, and their use in the UK, under the Health Service Products (Provision and Disclosure of Information) Regulations 2018. These require manufacturers, wholesalers and pharmacies to provide summaries of products sold and prices paid. Ministers can request more detailed information if required."—[*Official Report*, 4/11/20; col. GC 324.]

Given this access and the known sensitivities about falsified medicines directive data, it is unclear why the department has included this sweeping provision in Clause 3(1)(b). I described this as "legislative creep" at Second Reading. It goes well beyond the EU falsified medicines directive of 2011 and the associated delegated regulation of 2016. Of course, this was not acknowledged in the Commons by the Minister, Jo Churchill. As a result of the efforts of several noble Lords, the changes proposed to the FMD provisions are now out in the open—but that does not make it any more acceptable.

This might seem rather a specialised part of the Bill, but clarity about the scope of Clause 3 is vital if we are to have confidence that a suitable scheme for falsified medicines data will be put in place that does not go well beyond the current scheme in terms of the sensitive data that is collected and used. I hope the Minister can do better than last time in giving greater assurance about the ambit of Clause 3 so that I do not need to divide the House. I beg to move.

Lord Hunt of Kings Heath (Lab) [V]: My Lords, it is a great pleasure to support the noble Lord, Lord Clement -Jones, and my noble friend Lady Thornton. I urge the Minister to respond, as the noble Lord asked, on how Clause 3 will actually be used. It did not help that the Explanatory Notes made no mention of what the noble Lord described tonight and at Second Reading as "legislative creep".

We have had submissions from a number of organisations that make the point that the wording goes beyond the current EU legislation, which was carefully implemented after extensive consultation with the relevant bodies. That is from the Company Chemists' Association. The ABPI said that the falsified medicines directive was introduced as a barrier to counterfeit and falsified medicines entering the supply chain, thus reducing the potential risk of harm to patients, that the ABPI and its members have worked to fund and implement the falsified medicines directive, and that any future considerations under this clause must include full consultation with industry.

So there is general concern in the industry about how the clause will be used. We know that the department already has access to a wide range of data on medicines sales and use in the UK under the Health Service Products (Provision and Disclosure of Information) Regulations. Given this and the known sensitivities around falsified medicines data, I am still unclear why the department wants to extend the purposes for which data is collected under a future UK system. I know that we were very privileged—

Baroness Penn (Con): My Lords, unfortunately the noble Lord cut out again briefly. If he could rewind about 30 seconds, that would be appreciated.

Lord Hunt of Kings Heath (Lab) [V]: I am sorry, I have had a very poor connection tonight. Can you hear me now? All I was going to say was this: we were privileged to have a discussion with the noble Lord, Lord Bethell, and his officials before Christmas. The impression I had was that this is regarded as a useful clause to be used at some point in the future when a clearer purpose has emerged. I do not think that this is the way we should go forward. Like the noble Lord, Lord Clement-Jones, I hope the Minister can give some assurances tonight about how this clause and the information stored will be used.

8.15 pm

Baroness Jolly (LD) [V]: My Lords, this amendment, led by my noble friend Lord Clement-Jones, would narrow the use of data in relation to falsified medicines to that which ensures patient safety. The use of patient data is a really delicate issue. As currently drafted, Clause 3 allows for regulations to be made about

"the use, retention and disclosure, for any purpose to do with human medicines, of information collected for the purpose of preventing the supply of falsified human medicines."

The Minister has said that we want to explore creative uses of information. I am not quite sure what the general public would think of that statement. I am not quite sure what I think of that statement. As my noble friend Lord Clement-Jones has said, this is an incredibly wide remit granted to the Government. Restricting it to information that ensures patient safety, as in the amendment, will help protect patients' information. In his summing up I would like the Minister to outline how this amendment will work in practice, and we will consider whether this might be brought back at Third Reading.

Baroness Thornton (Lab): I am grateful to the noble Lord, Lord Clement-Jones, for his full and comprehensive explanation of the background thinking behind this amendment. It is clearly important that we understand and have clarity about the scope of Clause 3, and it is that clarity we seek from the Minister this evening. As my noble friend Lord Hunt said, we are urging the Minister to respond about how Clause 3 might be used. It is not good practice when you are law-making to put something in a Bill that might just come in useful at some point. The House probably needs a wider explanation and reassurance about this clause and how it will be used.

Lord Bethell (Con): My Lords, I am enormously grateful for that helpful debate. Let me try to provide some of the clarity and reassurances noble Lords have sought. Amendment 14 to Clause 3 would add constraints to the use of data collected as part of the operation of any national falsified medicines scheme. I understand that the intention of Amendment 14, in the name of the noble Lord, Lord Clement-Jones, is to prevent the use of data collected for any additional use other than for the purpose of ensuring patient safety. We discussed this at length in Committee and afterwards, and I am grateful to the noble Lord and to other noble Lords who have given up their time to discuss this important issue. I know that the noble Lord has returned to this because he thinks it is worth continued debate, so I would like to reassure him that we have thought very carefully indeed about the power in Clause 3(1)(b).

[Lord Bethell]

I will start with the context of the power to use information collected as part of any potential future national falsified medicines scheme. First, it is important to note that the overarching principles of the Bill set out in Clause 1 also apply to, and are constrained by, the powers in Clause 3.

Amendment 4 in my name would ensure that in making regulatory changes under Clause 3—not just around how information will be used—the appropriate authority's overarching objective must be safeguarding public health. In making that assessment, one of the things the appropriate authority must have regard to is the safety of medicines. Further, we have provided for a clear and unambiguous lock on patient safety; that is, as part of the decision-making process behind regulatory changes, if proposed changes have an impact on the safety of human medicines, the appropriate authority may make those changes only if the benefits outweigh the risks.

Secondly, of course, any regulations providing a framework for the use of the information will be subject to parliamentary scrutiny under the draft affirmative procedure. So, the scope of Clause 3(1)(b), which is the focus of our discussion, is not unfettered. I have discussed previously the statutory requirement to consult before making regulatory changes. Powers at Clause 3(1)(a), (2) and (3) will provide us with the means to make the regulatory changes to establish a verification system, if appropriate. As part of the effective operation of any such system, information will need to be collected. It is only once we have established the need for a verification system, and how it could work, that we can fully consider how the information it collects could be used to deliver additional benefits for the UK and for patients. Clause 3(1)(b) and (3) enable us to make appropriate best use of the data collected as part of a national focused scheme and ensure that the appropriate authority must have regard to the importance of ensuring that information is retained securely.

I want to reassure noble Lords by being as clear as I can that the data in question is that which would be collected for the prevention of the supply of falsified medicines—that is, as part of the operation of any verification scheme. I reassure noble Lords that we could not expand the data being collected using Clause 3(1)(b) as part of a verification scheme. However, we want to maximise the use of data collected as part of any verification scheme where it is in the public interest. In this, we would be learning from the EU scheme, which, for example, allows data to be used beyond patient safety for reimbursement purposes and in delivering a solution that works at a national level. I reassure the Chamber by being as clear as I can be that the powers in Clause 3 do not include the collection of patient data. As with the current European scheme, there are no plans for any future national falsified medicines system to collect patient data.

My concern is that putting such a limit on the use of information at this time could constrain or limit options ahead of our engagement with stakeholders. Critically, it may not allow for the data to be used for all potential research purposes. We are not in a position at this moment, ahead of our engagement with stakeholders, to list all the potential ways in which data sources might be combined for research and wider public health purposes, which can go beyond patient safety. We want to be guided by our stakeholder engagement and not to restrict that process unnecessarily before we have had a chance to hear how this data could be used for public interest purposes.

We are also proposing a staged approach to engagement and consultation. We are committing to a clear and separate consultation and engagement: first, a consultation around the need for and details of any system concerned with the prevention of falsified medicines; and secondly, a specific consultation around other uses of the data collected under Clause 3(1)(b). As I have said, any regulatory changes that will provide a framework for the use of the information would be subject to parliamentary scrutiny under the draft affirmative procedure.

I believe that by developing these proposals through consultation and engagement, we are improving our policy-making and its subsequent implementation. I remind the House that we have no scope for changing these provisions at Third Reading, so if the noble Lord, Lord Clement-Jones, wants to press the matter, he will need to do that today, but I hope instead that he will have had enough clarity and reassurances from the Dispatch Box to be able to withdraw his amendment.

Lord Clement-Jones (LD) [V]: I thank my noble friend Lady Jolly, the noble Lord, Lord Hunt, and the noble Baroness, Lady Thornton, for their helpful contributions and support today. I also thank the Minister for his reply; I regard it as something of a curate's egg, but I recognise the thought that has gone into it, particularly his statement on the overarching principles in Clause 1 governing Clause 3 and the fact that the benefits must outweigh the risks in any scheme. He talked about the affirmative procedure; I very much hope that we will retain the super-affirmative procedure, which encourages me that there will be greater scrutiny of any new framework.

The Minister also spoke about the statutory duty to consult on proposals and the duty to secure data. He said that no patient data was being used and that, at the end of the day, the essence of this is to maximise the use of data where it is in the public interest. He gave research as an example that might be outside patient safety—I doubt it, but he thought it might be interpreted as going beyond patient safety. I was very struck by the noble Baroness, Lady Thornton, saying that there was an element in this of having a power that might come in useful; indeed, the Minister almost repeated that in saying, "We'll see what data we have collected."

I take some comfort from what the Minister has said. We have had some very productive debates and some important amendments secured, so I will not press this amendment today. However, the noble Lord probably has to suffer the potential of being immortalised on a Pepper v Hart basis if there is any subsequent dispute about the width of regulations made under this clause and whether Clause 1 limits the scope of Clause 3. I am sure he looks forward to that. In the meantime, I beg leave to withdraw my amendment.

Amendment 14 withdrawn.

The Deputy Speaker (Lord Alderdice) (LD): We now come to the group consisting of Amendment 15. 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 15

Moved by ***Lord Field of Birkenhead***

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

"Entitlement of a doctor to prescribe medicinal cannabis products

The appropriate authority must by regulations make provision to—

(a) grant authorisation to place on the market of the United Kingdom high quality, standardised medicinal cannabis products for prescription by a doctor (including, for the avoidance of doubt, by a general medical practitioner),

(b) permit doctors to prescribe medicinal cannabis products, and any device or article that is required in the administration of such products, and

(c) require the relevant regulatory and advisory bodies to obtain and evaluate relevant scientific and medical literature and data, including on long-term patients' experience in connection with cannabis for medicinal use (as well as the potential for such use) with particular reference to—

(i) the efficacy and therapeutic value of medicinal cannabis products,

(ii) matters pertaining to the safety of medicinal cannabis products, and

(iii) the medical conditions (indications) in respect of which medicinal cannabis products may be administered and used."

Lord Field of Birkenhead (CB): I beg to move this amendment in my name and those of other noble Lords whom I count as friends. It is quite clear what the amendment is about; we list it at the very top:

"Entitlement of a doctor to prescribe medicinal cannabis products".

It is an enabling clause to allow that to happen. The debate today is not really about whether we have been clever enough to draft an amendment which will satisfy the Government, but about whether there is the will in Government to make a change that will affect a large number of people in this country, myself included, who use cannabis as a product to counter pain.

We have heard the urgency in today's discussions, and Oral Questions, to look at the plight of those little children whose brains are shaken to bits and beyond repair if they do not have access to this product. I would not want to be in the ministerial positions which have to decide how many more days those children must wait before their parents can obtain supplies which will abate the terrible effects of these endless fits, which come like the second hand on a clock, devouring their intelligence and ability to lead a proper life.

The debate is about whether the Government will make this change so that those doctors who wish to prescribe medical cannabis products are free to do so. We are not doing so in a form which, I hope, anybody could consider as irresponsible. We know that there need to be checks and that there are dangers with all medical products. But we have seen recently a wonderful example of the political will which decided that as soon as a vaccine was ready to distribute, providing that safety was ensured, that drug would be rolled out. I hope one of the things we will get from this evening's short but important debate will be a commitment from the Government that the speed shown to protect the whole population from Covid will similarly be displayed when we come—I hope at some stage soon—to agree the distribution of medical cannabis via the NHS rather than privately.

8.30 pm

It is rather appropriate that I discovered the world of campaigning on this product when I was involved in a minor role in trying to advance the interests of those children. I must say, to hear parents who are remortgaging their homes to buy the products for those children is pretty grim for somebody like me, who can acquire these products, quite legally, because they have the money in the bank to do so. It is not a principle which I think many in this noble House would agree with. We are anxious not only about the issue with Alfie, who was one of those very people when I first was engaged in this issue. Maybe we will have news from the Minister tonight about an agreement that has been made so that there will not be another day where those children are vulnerably exposed to the will of their bodies, which causes such destruction of their long-term futures.

I quite understand the need for political courage on this issue. Is it not amazing that I have to say that, when we are talking about maybe a million or more people who depend on this drug to counter the pain which they suffer, and that we should be talking in such terms? I do believe that there will be a change soon in these regulations and that we will move to a more civilised position, where people who have tried—as I did—all other traditional methods of controlling pain and then find a way of doing so will be able to secure this product on the NHS rather than because they possess enough private resources to do so.

It is an immensely important topic which, I think, Members of the House will be pleased to know we are not going to extend by reciting the same speeches that we have already given. We will want the key debate to take place—though it cannot—once the Minister has spoken and told us where the Government's thinking on this issue is. I move the amendment in this brief way not because it is a topic lacking in importance; I hope the brevity will be taken as a sign of concentrating on the issue itself.

I very much hope that there will be a demonstration of the will of this House which strengthens the Government's position in making a change in policy, particularly from the Home Office, which has the main leave now, to the Department of Health where, of course, this issue belongs and should be settled. I hope very much that we will get a very clear steer from the Minister on what the Government's plans are in looking at this reform before the Bill goes into the Commons. Therefore, I beg to move the amendment which stands in my name and the names of my noble friends.

Baroness Meacher (CB) [V]: My Lords, I have added my name to the amendment moved by my noble friend Lord Field of Birkenhead. I want to give it my strongest possible support, as Ministers will expect of me.

In November 2018, the significant medicinal properties of cannabis were finally recognised after 50 years of misinformation—I can only call it that—about the plant. At that time, around 1 million patients thought, "Oh my goodness, we're going to be able to obtain our medicines free of charge through the NHS." How wrong we all were. I think I am right in saying that only three prescriptions have been written under the NHS since that date; in my view, that is some indication of the degree of misinformation over so many years.

The epilepsy crisis illustrates powerfully that the right medical cannabis is essential for the treatment of severe epilepsies that are resistant to standard medications. I understand that Ministers know this well and are doing what they can behind the scenes. I know that the noble Baroness, Lady Walmsley, will focus strongly on this particular issue.

I want to mention an economic point, if you like. Until his parents so brilliantly found medical cannabis, dear Alfie Dingley's terrible emergency ICU admissions —nearly every week—were costing the NHS around £100,000 a year. That included his consultant cost, GP costs and medications. The reality is that this amendment could save the NHS hundreds of millions of pounds. It is absolutely crazy to make this so difficult.

The aim of our amendment is to ensure that medications such as Bedrolite, which saved Alfie's life—I do not think that that is an exaggeration—could receive marketing authorisation, thus immediately resolving the problem for Alfie and other children like him. The fact is that Bedrocan products have been used very successfully for decades, showing that they are both safe and effective.

As my noble friend Lord Field of Birkenhead said, the amendment would solve the problem not only for epileptic children, terribly important though that is, but for the very many people who suffer severe chronic pain, particularly neuropathic pain. It would open the way for cannabis products with a track record of efficacy and safety to be given marketing authorisation and prescribed by GPs as licensed products. That is what we want to achieve here.

I want to make a few further comments. I hope that I am reflecting correctly the comment of June Raine, the chief executive officer of the MHRA, in a Zoom meeting in which we were both involved. She seemed to suggest that, finally, she understood that the MHRA needs to take real-world experience much more seriously. If this is what she meant, I applaud her most strongly; I have been waiting for a senior person in the MHRA to take that view for some time.

If a patient has many years of experience of medical cannabis and has found that it really helps them when other products had not done so, surely this experience should be taken very seriously, not only by the MHRA but by doctors too. Cannabis should be prescribed for the patient in question and other patients with similar conditions. I therefore plead with the Minister, the noble Lord, Lord Bethell—for whom I have the greatest respect on a whole range of issues—to encourage the MHRA to revisit its rules for assessing the efficacy of medical cannabis, to take account of the real-world experience I have mentioned.

I am not talking about a few patients or a few weeks of trying something out—not at all. The fact is that 78 medications prescribed within the NHS have never been through random control trials. It is simply not true to say that medical cannabis products must go through such trials. The complexity of the cannabinoids in cannabis is such that RCTs tend to lead to suboptimal products being approved as single cannabinoids when in fact several cannabinoids and some terpenes might be a great deal better.

Another aspect of real-world experience is the research undertaken in other countries. The National Academies of Sciences, Engineering and Medicine published the report *The Health Effects of Cannabis and Cannabinoids* in 2017, more than three years ago. It was a review of global research into the efficacy of cannabis medicines. Already, three years ago, it was able to conclude:

> "There is substantial evidence that cannabis is an effective treatment for chronic pain in adults".

Since then, the WHO has finally recognised the medicinal value of cannabis. More and more countries are also recognising the facts about this important medicine. The UK is now lagging behind the English-speaking world. It is really time to catch up, and I hope that our Minister can help us.

My last point concerns our own police forces. Many have now moved ahead of the Government in deciding not to arrest patients who have a few plants in their kitchen to supply themselves with their medicines, or even those who get such medicines from illegal dealers—let me tell you, that is the last thing patients want to do. The police know perfectly well that it is cruel to add a criminal offence to all the pain that these patients already go through.

I hope that the Minister will be willing to meet the noble Lord, Lord Field, and I, ideally with June Raine, to discuss the best way forward. I believe that to improve access to medical cannabis for patients, Ministers will need to adjust the regulations that currently restrict that access and prevent GPs prescribing medicines that patients so desperately need.

Baroness Walmsley (LD) [V]: My Lords, I am honoured to follow the noble Lord, Lord Field, and the noble Baroness, Lady Meacher. I too have put my name to Amendment 15.

Before I specifically address the amendment of the noble Lord, Lord Field, I would like to acknowledge the Minister's reply to my Oral Question earlier today about the negative effect of Brexit on the legal supply of Bedrocan, and probably other cannabis medicines, to patients in the UK. He knows that this is a life-changing and life-saving medicine, so he will understand that patients and their families are very anxious. Can he assure me that they will be kept informed about progress on sorting this out? They and their clinicians were very worried by his suggestion that there needs to be compromise on both sides. There can be no question of compromise; it would be dangerous to try to substitute this medicine for a different formulation, extracted from a different strain of cannabis.

In response to the DHSC's suggestion to pharmacists that one cannabis medicine can easily be replaced by another, I will quote from evidence that I have received from Evan Lewis, director of the Neurology Centre of Toronto. He is a clinician with extensive experience of medicinal cannabis for adults and children, and has said:

"It is imperative that children who are benefiting from a particular medical cannabis product are not changed to another product. There is significant variation from one product to the next, and many unknowns as to how all the cannabinoids interact with each other to treat seizures".

He goes on to say that swapping backwards and forwards between products can be extremely dangerous and is often ineffective. This misunderstanding nicely illustrates some of the problems we face in our campaign to make the benefits of cannabis medicines more widely available to UK patients on the NHS.

On the wider issues in Amendment 15, the key issue is how evidence is obtained about the safety and efficacy of these medicines. I see the Government's fixation with random-controlled clinical trials as a real barrier to progress in the field of cannabis medicine. When scientists are trying to investigate any issue, they always use procedures that are appropriate to the material being investigated and to answering the question asked. When you have a very small patient cohort, such as the cohort of children with drug-resistant epilepsy, it is impossible to have a meaningful clinical trial. Besides, when giving a placebo to half the sample could be life-threatening, it could be unethical.

As the noble Baroness, Lady Meacher, said, many drugs and medical devices are already used on an anecdotal basis. For example, as she said, 78 drugs are available and in use in the NHS that have no random control trial. The vagal nerve stimulator, which is successfully used to prevent seizures in some epileptic patients, also has no RCT in relation to it. There are many drugs used on children that have not been tested in clinical trials for use in children. Indeed, some of them were used on Alfie Dingley and the other children who now receive cannabis medicines before they fortunately discovered the benefits of the latter.

8.45 pm

These drugs are used off-label. This is a well-used way of prescribing in the NHS. Unfortunately, clinicians are being deterred from prescribing cannabis medicines in this way by very negative government messaging, and are even threatened with sacking by their health trust. They also need more information on these matters.

It would be appropriate to set up a formal system of observation, recording and clinical evaluation of these products in use in the UK, alongside accepting the mass of evidence from other developed countries. Such observational studies are not the same as anecdote and would most certainly result in the acceptance of the safety and efficacy of these products for certain indications. Such evidence should then be included in medical education, particularly for neurologists and general practitioners, so that they can have the confidence to write free NHS prescriptions for patients who could benefit from cannabis medicines that have been used safely for years elsewhere.

I hope the Minister is able to tell us in response what appropriate system the Government are prepared to put in place as an alternative to clinical trials, so that UK patients can have the benefits that patients in the Netherlands, Canada, the United States and many other countries have had for years.

Baroness Masham of Ilton (CB) [V]: My Lords, I thank the noble Lord, Lord Field of Birkenhead, who moved this amendment so movingly. This debate has gone on for many years.

It has been found by parents that medical cannabis can help some children who have multiple seizures due to epilepsy. I need to know: has NICE approved it? If it is waiting for more research, there will have to be more people using medical cannabis so that the information can be collected. If it is helping, doctors who understand the problems need to be the people who prescribe it. It should be carefully monitored. If it gives better quality of life, why should it not be prescribed? I hope the Minister will do his best to see that it is.

Lord Hunt of Kings Heath (Lab) [V]: My Lords, I am really grateful to the noble Lord, Lord Field, and the noble Baronesses, Lady Meacher and Lady Walmsley, for sponsoring this amendment and for the powerful speeches they have given.

Last week, I heard Hannah Deacon talk on the "Today" programme about her son Alfie and the devastating consequences of Brexit and the impact of the inability to import Bedrocan from Holland. I know the Government have been active, and I very much hope the Minister will be able to report progress tonight.

That is the immediate issue, but of course there is then the long-standing issue that, when Parliament agreed to the legalisation of medical cannabis under prescription, there was a distinct impression that NHS patients would receive medical cannabis where appropriate. It is very clear that the NHS is not prepared to do that. The small number of prescriptions and the approach of the various bodies that advise the health service on commissioning make it abundantly clear that, unless Ministers intervene, patients will simply not be able to get these products in a legal way.

I say to Ministers that, with the campaigns, it is obvious there will be increasing noise, increasing concern. They really will have to step in and find a way of getting access to these products for patients. It is inevitable that it will happen, and it is better than they do this now rather than wait for another three, four or five years. I remind them that, when the legislation went through, the Home Secretary at the time said:

"We have now delivered on our promises … we will work with the NHS to help support specialists in making the right prescribing decisions."

That simply has not happened.

I suggest four approaches: first, the All-Party Parliamentary Group on Medical Cannabis under Prescription believes that the only way to help families at the moment, and to make sure the policy does not stall completely, is to set up a small fund called something like the medical cannabis access fund, which can be used to help those families, until the blockage on NHS prescription eases.

[Lord Hunt of Kings Heath]

Secondly, we have to come to the issue of research. I know the Minister is frustrated—he repeated this today—because he thinks the companies producing these products should come forward and undertake clinical trials and tests. I am not an expert, but I have listened very carefully to noble Lords and to advice that I have received, which suggests that randomised control trials are very difficult in this area. In that case, surely the Government should revisit the NHS England report, *Barriers to Accessing Cannabis-based Products for Medicinal Use on NHS Prescriptions*. The report looked at the issue of research, and said that there should be randomised controlled trials but, alongside this:

"NHS England and NHS Improvement and NIHR in conjunction with the specialist network will work together to determine an appropriate alternative study design that will enable evidence generation for those patients who cannot be enrolled into a standard RCT."

I gather that this has not happened. The Minister really should inquire into this. It would basically be an observational study; it would allow medical cannabis to be prescribed for large numbers of people and for proper research to be undertaken. I suggest to him that it would be a way forward, so that the current frustration of so many patients is responded to in a sympathetic but also practical way.

Baroness Bennett of Manor Castle (GP) [V]: My Lords, we started this debate today with widespread plaudits to the Government for listening to very strong campaigns to have a patient safety commissioner. Indeed, the noble Baroness, Lady Cumberlege, who has been so instrumental in this, commented on the importance of that person listening to patients. We have to draw the parallels here because we have heard—as a community, as a society, and as a Parliament—from the parents of children who desperately need these medicines but are unable to access them. Those patients are not being listened to. We really do have to ask ourselves the question of why that is happening and what kind of political block or ideological barrier exists so that we are not seeing action in this area when it is so clearly, urgently needed.

When we were talking about a patient safety commissioner, I commented on how effective campaigning has been in that area. There is also a very effective campaign called End Our Pain, which has been working with families trying to access this medicine. It has been doing a great job, but the Government have not been doing their job in delivering on the campaign. I give credit to the noble Lord, Lord Field of Birkenhead, and all the other people who have signed this amendment, which is very much cross-party and across the House. As the noble Lord said, we have a division here—a human rights issue, referred to in the amendment tabled earlier by the noble Baroness, Lady Sheehan. People, or families, who can afford it, are able to access this medicine; those who need NHS support for it cannot. We should not be tolerating that situation in Britain at any time, particularly in 2021.

I have a direct question for the Minister. I have been looking at what assessment the Government might have made of the impact of current policies and the lack of financial support for vulnerable families. I should be happy to be corrected and perhaps told that an assessment is under way, but the most recent information that I was able to find was from September last year, when Liz Saville Roberts MP asked a Written Question in the other place about whether such an assessment had been made—and the answer was no. I will be brief, because the issues have been well set out by the noble Lord, Lord Field, and others. However, I ask the Government what assessment they have made of the impact of their current policies.

Baroness Jolly (LD) [V]: My Lords, today's final amendment, tabled by the noble Lord, Lord Field of Birkenhead, and signed by my noble friend Lady Walmsley and the noble Baroness, Lady Meacher—all long-term campaigners on this issue—would require regulations to be introduced to allow doctors to prescribe medicinal cannabis products. I know that the movers of the amendment have been campaigning for ever—probably as long as I have been in the House—and can be excused their despair at the inactivity of GP prescribers.

The Home Office changed the status of medicinal cannabis two years ago, after a long campaign, but it has not been widely prescribed. The need for clarity on this matter was brought to the forefront by the news that nine year-old Alfie Dingley, whose use of medicinal cannabis has greatly improved his health, is no longer able to access his medication from the Netherlands due to Brexit. The Lib Dems have long been advocates of making medical cannabis accessible to those whose health would greatly benefit from it, and we support this amendment.

Will the Minister tell us what she can do to persuade the medical profession that cannabis has real medicinal value? Why are doctors deaf to children such as Alfie, and why are children such as Alfie and his parents left in the lurch? I hope that the Minister will be able to accept the invitation from the noble Baroness, Lady Meacher, to join her in a meeting with Dr June Raine, the chief executive officer of the MHRA.

Baroness Thornton (Lab): The noble Lord, Lord Field, will know from this afternoon's Question that I have huge sympathy on this issue, and I also completely recognise the frustration that exists around this subject. As I said earlier, "Come on, Prime Minister: if you can solve Brexit, in your own terms, I am sure that you will be able to solve this one, too."

"Irresponsible" is not a word I would use to describe the noble Lord, Lord Field. He was very temperate in his introduction of the amendment. It is shameful, as the noble Baroness, Lady Meacher, said, that only three prescriptions have been issued properly by the NHS for free use. That means there is something is seriously wrong here. I thank my noble friend Lord Hunt, who is quite correct: this does require political muscle. The noble Baroness, Lady Bennett, is quite right, because this issue also completely exposes the inequalities we see in our society, whereby people who are fortunate enough to be able to afford to buy cannabis products can do so, while those who cannot, cannot, and then they suffer the consequences of that—literally. The noble Baroness, Lady Jolly, mentioned despair, and I agree with her.

So I do think that, as a result of this short but very potent debate, the Minister needs to commit at least to the meeting with the MHRA and the movers of the amendment.

9 pm

Baroness Penn (Con): My Lords, Amendment 15 in the name of the noble Lord, Lord Field of Birkenhead, deals with a topic that has been discussed at length in both Houses. The noble Lord spoke eloquently in Committee, sharing his experience of medicinal cannabis and the benefits he obtains from it.

I will first address a separate but related matter that a number of noble Lords raised concerning the supply of certain cannabis-based medicines from the Netherlands. I know that the noble Baroness, Lady Walmsley, and others in the House have received distressing calls from patients and families who have relied on these imported medicines. The Parliamentary Under-Secretary of State for Prevention, Public Health and Primary Care, Jo Churchill, met Alfie Dingley's family and the patient group End Our Pain on Saturday to provide reassurance and an update on the action that we are taking.

I reassure noble Lords that we are working urgently with the Dutch Government to find a solution that will enable patients to access the medications they need. I cannot discuss the details of the proposals today, but I commit to provide noble Lords with a further update when I can.

Returning to the matter at hand, I reassure noble Lords that the issues raised by the noble Lord, Lord Field, in his amendment sit firmly with the Department of Health and Social Care, not the Home Office. While I am pleased that the noble Lord finds some relief with this medicine, the fact remains that the vast majority of cannabis-based medicines have not been assessed by the MHRA for safety, quality and efficacy, nor by the National Institute for Health and Care Excellence for clinical and cost effectiveness. I believe that that is the nut that the noble Lord is trying to crack with his amendment. We are also trying to crack it as a Government, but from a slightly different approach.

As the noble Baroness, Lady Meacher, noted, the Government changed the law on 1 November 2018, to reschedule cannabis-based products for medicinal use in humans. This moved these products from Schedule 1 to the Misuse of Drugs Regulations 2001—no legitimate use—to Schedule 2, to permit the lawful prescribing and supply of cannabis-based medicines when certain criteria are met. In particular, cannabis-based medicinal products can be prescribed by one of three routes: as a "special medicinal product", subject to the "specials regime" contained in the Human Medicines Regulations 2012, prescribed by a specialist medical practitioner; as an investigational medicinal product for use in a clinical trial; or as a medicinal product with a marketing authorisation.

Given that there is insufficient evidence on the safety, quality and efficacy of these unlicensed medicines, it is entirely appropriate that these products are subject to these stringent conditions. It would be inappropriate to establish parallel arrangements or to subject medicinal cannabis to any less stringent assessment than is the case for other medicines used for serious or chronic conditions. To do so would undermine the integrity of our medicines regulation in the UK. Also, it would run counter to the noble Lord's objective to see the placing on the market of high-quality, standardised cannabis-based medicinal products that are safe and effective.

As noble Lords heard in Committee, we have removed some of the barriers to how these products are imported into the UK and we now see a wider range of products available to prescribers. I reassure noble Lords that we are also taking steps to improve the body of evidence available. NHS England and NHS Improvement have made good progress to establish a national patient registry for patients receiving medicinal cannabis. This has been developed with clinicians and aims to cover all clinical indications and all licensed and unlicensed medicinal cannabis products prescribed on the NHS and privately. The registry will be an important step forward in the collection of uniform data to support monitoring and evaluation of prescribing activity, patient safety and clinical outcome data. This data, and that produced from clinical trials, will help inform future NHS commissioning decisions. The registry is currently being piloted, with a view to further rollout next year.

On clinical trials, the National Institute for Health Research and NHS England are working together to set up a programme of two randomised controlled clinical trials. These trials will be critical in ensuring that evidence for cannabis-based medicinal products can be developed to inform future NHS commissioning decisions for the many hundreds of patients in the UK with refractory epilepsy. This is a pioneering area of research and we hope the trials will start as soon as possible. However, I must emphasise that industry also needs to step up and invest in robust clinical trials to improve understanding of how patients might benefit from these products.

I must say to noble Lords that it is not the job of the independent regulator to generate evidence. To do so would undermine the independence and objectivity of medicines regulation in this country, including the pharmacovigilance of medicines. The safety of the public will always come first, and the producers of medicinal cannabis must be prepared to subject their products to scrutiny by the MHRA and by NICE.

When marketing authorisations are sought, they will be dealt with by the regulator, as with any other medicine, taking into account their herbal origin. The MHRA offers, and has given, regulatory and scientific advice to companies and researchers to support their research and development of these products. I reassure noble Lords that the MHRA is committed to using the latest techniques and takes a patient-centric approach to medical regulations.

Regarding further discussion of this with the MHRA, I will take that request away. I think we all welcomed June Raine's approach in the meeting with Peers last year on this Bill. I am also conscious at this exact moment in time of the pressures on the MHRA to support our national effort on vaccination rollout. I am sure we will get a positive response, but there might be a small issue around timing that we will have to take away and address.

[Baroness Penn]

As we have seen with the Pfizer and BioNTech Covid vaccine, and, indeed, with the other Covid vaccines that have come online, the MHRA upholds the highest standards and will authorise the use of medicines only following the most rigorous scientific assessment. This is essential to ensure that the public can have trust in the regulator and the medicines they use. Licensed products, such as Sativex for multiple sclerosis and Epidyolex for rare epilepsies, have gone through this process and are proof that cannabis-based products can meet the high standards of quality, safety and efficacy that we rightly expect in the UK.

On that basis, and on the basis of the Government's ongoing efforts to ensure that we have a strong evidence base to provide further access to these medicines, I ask the noble Lord, Lord Field, to withdraw Amendment 15.

Lord Field of Birkenhead (CB): My Lords, I can willingly agree to that last request. I think if we put it to a Division we might not win, so what is the point of closing doors when the Minister was busy opening them? I am immensely grateful to her for that.

As the House can see, many people can do two things at once—both speak and keep their masks in place. I fail that test. But I want to thank those who have participated—the noble Baronesses, Lady Meacher, Lady Walmsley, Lady Thornton, Lady Masham, Lady Jolly, Lady Bennett and Lady Penn, and the noble Lord, Lord Hunt—for their contributions in taking this debate further.

If I may, I will end on a cheerful note. Let us suppose that, in the next few days, the Prime Minister finds the time to look at this issue and decides that the Government's line will be different. We know that the people who have had to defend the line tonight would then put another case to us, and I hope that that case will be put very shortly.

Safety is, of course, crucial. However, we have just experienced the introduction of the Oxford vaccine and other vaccines. Presumably they went through randomised controlled trials, so those can be accomplished very quickly. I hope that, when the Prime Minister changes his mind, we will move to testing the safety of these products as quickly as we have the vaccines. Just as the vaccines offer us hope of life after Covid, I hope that we will see a quick response for those millions of people who are not free to obtain their cannabis on the NHS but who, like me, are lucky enough to be able to buy it. I hope that we will move very quickly and resolutely. One way of levelling up is to make these products—once their safety has been established—free for everybody on the NHS.

Amendment 15 withdrawn.

Consideration on Report adjourned.

House adjourned at 9.10 pm.