

We expect the Government to address this issue at second reading without the need for a probing amendment.

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medConfidential amendment to the Organ Donation (Deemed Consent) Bill¹

Clause 1, page 2, line 15, leave out “other than relevant material”

Explanation:

The regulation shall explicitly list tissue and organs that are subject to deemed consent.

Current text in clause 1(5):

“permitted material” means relevant material other than relevant material of a type specified in regulations made by the Secretary of State. 15

becomes:

“permitted material” means relevant material of a type specified in regulations made by the Secretary of State.

Details:

An explicit list of tissue and organs deemed consented is fundamentally clear and transparent to Parliament, to the medical profession and to the public, on a topic where indirection should be avoided.

The Bill as currently drafted creates an ‘exclusion list’ of transplantable material to be excluded from the opt-out. This is the wrong way round, and potentially confusing to the public at large – the regulations passed by Parliament should simply contain a list of tissue and organs that are covered by the opt-out.

The Bill as currently drafted would result in the following process:

- 0) *An organ / piece of tissue is currently impossible to transplant...*
- 1) Medical research makes some new transplant possible – but novel, and possibly controversial
- 2) Parliament is then required to pass a Regulation to add it to the opt-out exclusion list
- 3) After some time, medical research and public awareness moves forward to the point where that transplant is “common” and uncontroversial
- 4) Parliament is then required to pass a Regulation to remove that transplant from the exclusion list.

In such a scenario, until or if Parliament does not act, then that organ or tissue will be subject to deemed consent – which may potentially include uses other than transplant, such as some forms of tissue research. The process also requires Parliament to decide two things

¹ <https://publications.parliament.uk/pa/bills/cbill/2017-2019/0268/180268.pdf>

(and to explain why it has changed its mind, which may be a high bar), when it should only need to decide once (a decision that should prove more straightforward, as no action would be required during the period of controversy).

The Bill as currently drafted creates a list of prohibitions, but something will only be prohibited by Parliament after it is possible. Under this approach, a medical advance will necessitate a rush to Parliament, forcing Parliament into deciding an issue at what will almost inevitably be a sensitive time for evolving research.

Under the model proposed, there also is not – and cannot be – a comprehensive and explicit list for members of the public of what the opt-out actually achieves, since this also depends upon whatever research is in the publication pipeline.

Additionally, as the Bill is currently drafted, while the opt-out is about “donation”, the tests for Parliament are about “transplant” – there are uses of tissue other than just transplant which fall outside of the safeguards altogether. (These are primarily research, which is left in a grey area, being outside the dissent.)

By contrast, a list of the tissue and organs covered by the opt-out would be simpler, clearer and achieve Government’s stated aims – and give everyone full confidence as to how human tissue may be used after death, without also having to read the research literature to see what is new, and where Parliament has and hasn’t acted.

In short, this amendment allows Parliament to approve by regulation what tissue and organs come under the opt-out – and only those materials approved by Parliament are covered.

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