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Llywodraeth Cymru
Welsh Government

Eich cyf/Your ref
Ein cyf/Our ref LF/LG/0071/13

Mark Drakeford AM
Chair, Health and Social Care Committee
National Assembly for Wales

7

February 2013

Dear Mark,

Human Transplantation (Wales) Bill: Consultation submission from Professor John Fabre

Thank you for your letter of 30 January 2013 drawing my attention to the submission you received from Professor John Fabre of Kings College, University of London. I feel it is important to respond to the serious suggestions our Explanatory Memorandum is incorrect and our case for the Human Transplantation (Wales) Bill is not justified by the international evidence.

I have been provided with an overview of the robust international research attached, developed by our Social Research officials. This illustrates the wide consensus in research papers which consistently categorise Spain as a country with an opt-out system of legislation. It reiterates the conclusion of the research we published in December, that is opt-out laws are associated with increased organ donation rates and increased willingness to donate. I hope this analysis is helpful in considering Professor Fabre's comments.

We stand by the text of the Explanatory Memorandum. The Spanish Government's website points to the adoption of appropriate legislation as one element of the success of the "Spanish Model" for organ donation. We have always said while the law is just one part of the framework for a successful organ donation system, opt-out legislation influences societal behaviours leading to it being a norm across society. Clearly this is alongside the commitment for a comprehensive communication package.

I would add we are not seeking to emulate the law or practice of any particular nation. Some have reservations about the practice in Spain of approaching families repeatedly and

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with persistence. We are developing an organ donation system which is right for Wales, taking full account of international law, practice and evidence of outcomes.

Please let me or my officials know if we can be of any further assistance in considering the international evidence.

Your later letter of 5 February is receiving attention.

Regards
Lesley

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Academic literature and the organ donation system in Spain

The following papers – all judged to be methodologically robust by Rithalia et al (2008) and/or Welsh Government (2012) – found that opt-out systems for organ donation are associated with increased organ donation rates or increased reported willingness to donate:

Author(s)	Findings	Data
Gimbel et al (2003)	Countries that practiced presumed consent had, on average, and extra 6.14 donors PMP compared to countries that practiced informed consent.	Data from 28 countries from the years 1995-1999.
Healey et al (2005)	Organ donation rates were greater by 2.7 donors PMP in countries with presumed consent legislation compared to informed consent countries.	Data from 17 countries over period 1990-2002.
Abadie & Gay (2006)	Countries with presumed consent legislation had 25-30% higher organ donation rates than informed consent countries.	Data from 22 countries over the period 1993-2002.
Neto et al (2007)	Presumed consent countries produced 21-26% higher organ donation rates compared to countries with informed consent legislation.	Data from 34 countries over a five year period.
Mossialos et al (2008)	Individuals living in presumed consent countries were between 17-29% more likely to report willingness to donate their own organs and 27-56% more likely to report that they would be willing to consent to the donation of their relatives' organs, compared to respondents living in explicit consent countries.	Individual-level survey data from participants living in 15 European countries.
Bilgel (2012)	Countries with presumed consent legislation have on average 13-18% higher organ donation rates than countries with informed consent legislation.	Data from 24 countries over the period 1993-2006.

Of the papers, only Gimbel et al (2003) classify Spain as an informed consent country 'in practice'. However, Spain is omitted from the analysis as it is treated as an outlier. All of the other papers listed above classify Spain as a presumed consent country.

The Gimbel paper is notable for classifying other countries as informed consent in practice (including France, Italy and Norway) that other studies have classified as presumed consent. As noted by Rithalia et al (2008: 28), there is a difference between the legislation itself and how it is implemented in practice – and Gimbel classified countries according to their methods of implementation.

The study by Rithalia et al is a summary of the evidence on the impact of opt-out systems at the time, and noted that Spain's legislation was based on "presumed consent".

Rithalia et al provide further explanation of how organ donation consent laws function in practice in different countries, including Spain, which is defined as having a weak/soft version of presumed consent:

"In practice, the ways in which these laws function differ between countries and even regions. It is rare that a country will have a 'pure' informed or presumed consent system and it is common for there to be provision for the involvement of relatives within each legal system. The importance placed on relatives' opinions varies. The terms hard/strong and weak/soft have been used to describe the extent of emphasis placed on relatives' views. For example, though both Spain and Austria have a presumed consent law, in Spain the law is considered 'weak/soft' as doctors take active measures to ascertain that the next of kin does not object. In Austria the law is relatively 'strong/hard' in that organ recovery proceeds unless it is known that the deceased objected prior to death, and the views of relatives are not actively sought."

Rithalia et al (2008: 14)

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