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# Safer Medicines Trust

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**Human tissues are invaluable for medical research  
– how can we make them more available?**



## Summary of the proceedings of a conference in the House of Lords 20 October 2009

Audiovisual presentations available at [www.SaferMedicines.org/humantissues](http://www.SaferMedicines.org/humantissues)

Complete proceedings available from: Cell and Tissue Banking:  
[www.springerlink.com/content/104845](http://www.springerlink.com/content/104845)

or Safer Medicines Trust

Contact Kathy Archibald:

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Join the Human Tissues Working Party at:

[www.SaferMedicines.org/humantissues](http://www.SaferMedicines.org/humantissues)

or contact Margaret as above



the answer is in  
**tissue**

## Quotes from some of the authors...

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“Our unswerving reliance on animal tests for safety and efficacy in humans does not stand up to rigorous evaluation. It is now time to move towards more human focused testing for human medicines.”

**Dr Bob Coleman DSc, co-founder of Pharmagene, now Asterand, and Pharmaceutical Industry Consultant**



“Living human tissues can be used to really predict how a drug is going to behave in patients.”

**Dr David Bunton, co-founder and CEO of Biopta Ltd**



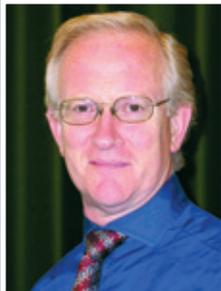
“The sky is the limit, beyond animal research, when it comes to human tissue engineering.”

**Dr Kelly Bérubé, Director, Lung and Particle Research Group, Cardiff University**



“Our aim is to develop new drugs to treat human disease, so using human tissue is an obvious way to go.”

**Iain Dougall, Principal Scientist, Discovery BioScience, AstraZeneca**



“If you really want to study human disease, you’ve got to study the human. Don’t try studying something else as a surrogate, however tempting it might look because it’s easier – you’re going to get the wrong answer.”

**Professor Chris Foster DSc, MRCS, FRCPath, University of Liverpool**



“The benefits of human tissue for research are vast. Donor families are happy to know in many cases that these tissues can be made available for research if not transplantable.”

**Dolores Baldasare, International Institute for the Advancement of Medicine**



“For too long we have used animal models for human disease. In the clinic, we treat patients, and therefore the most appropriate model is the human.”

**Professor Gerry Thomas, Hammersmith Hospital and Imperial College, London and Director of Scientific Services, Wales Cancer Bank**

## Proceedings of the human tissues conference, House of Lords, 20 October 2009: Introduction

Margaret Clotworthy

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**Abstract** On 20 October 2009, scientists and politicians gathered in the House of Lords to discuss the barriers medical researchers face when attempting to access surplus human tissues. Presently, such tissues, including those surplus to requirements for diagnosis after surgery, are all too often incinerated because patients' permission has not been sought for them to be used in medical research. A similar situation arises where organs which have been donated for transplant are unsuitable for donation. As a consequence of the conference, the Human Tissues Working Party was established to enable the discussions which began so fruitfully at the conference to continue, and to allow delegates, and participants who have joined subsequently, to present a unified case in submissions to public consultations, for example.

**Keywords** Drug safety testing · Human tissues working party · Animal tests

Last October, more than 50 scientists and politicians gathered in the House of Lords to examine the hurdles facing scientists who require access to human tissues in order to carry out their research, and to find possible

solutions. The conference was co-sponsored by patient safety charity Safer Medicines Trust and human tissues and services providers Biopta and Asterand. Stakeholders, including scientists from academia, biotech, the pharmaceutical industry, pathology departments and of course, biobanks, spoke enthusiastically on a range of subjects. *Cell and Tissue Banking* reported on the conference on 13 December.

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## Efficacy and safety of new medicines: a human focus

Robert A. Coleman

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**Abstract** The introduction of safe and effective new medicines is proving ever more difficult, a problem arguably due at least in part to over-reliance on experimental animal-based test systems. In light of the increasing awareness of the lack of predictiveness of such non-human approaches, the necessity to focus on human-based test methods is clear. There has been considerable progress in human in vivo (microdosing) and *in silico* approaches, primarily to identify ADMET issues, however, in vitro functional studies using human tissues are receiving inadequate attention. The potential scope of human tissue-based research is considerable, but much methodological development is required, which necessitates an increased willingness on the part of the Pharma industry to support it. This approach also requires considerably improved access to the cells and tissues themselves. While current acquisition is almost exclusively from surgery and *post mortem*, the range of tissue types, the quantity, quality and frequency of supply will remain inadequate to support human tissue as a key component of pre-clinical efficacy and safety testing. Additional routine access to non-transplantable tissues from organ donors for research purposes would be of inestimable value, but in order to realise this, true

collaboration will be required between NHS, the Pharma and biotech industries, and the general public.

**Keywords** Heart-beating donors · Drug safety · TGN1412

It is generally agreed that the pharma industry has a problem in bringing safe and effective new drugs to market. This may well be due, at least in part, to the over-reliance of the industry on using animals as human surrogates. Indeed, the most widely used animal species, rodents, dogs and non-human primates, have all been shown to be highly unreliable in their ability to predict drug behaviour in man. A comparison of the bioavailability of a range of drugs in man with that in these three species by Grass and Sinko (2002) demonstrated a very poor level of correlation. Furthermore, a retrospective study by Olson et al. (2000), showed that for some systems, the predictive value of animal studies to identify potential toxicity in human subjects performed little better than the spin of a coin. In the light of such low predictive power, it seems surprising that such store is set by animal safety data.

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# The use of functional human tissues in drug development

David Bunton

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**Abstract** Fresh, functional human tissues have long been considered the closest possible model of human in vivo function and can be used to measure a wide range of pharmacological responses. Despite this, relatively little drug development is conducted using fresh human tissue because of the logistical and ethical difficulties surrounding the availability of tissue and practicalities of experimental work. Most tests of drug activity require a living test system comprising cells, tissues or whole organisms. In some instances, “living” (fresh) human tissues have the potential to reduce or replace animal tests through superior prediction of drug safety and efficacy. Before functional human tissue tests become a routine part of drug development, two factors must co-exist. Firstly, organisations such as Biopta must continue to create compelling evidence that human tissues are more predictive than alternative models; such evidence will drive demand from the pharmaceutical industry for human tissue-based tests. Secondly, the vast number of tissues and organs residual to surgery or unsuitable for transplant must be routinely consented for medical research and made available to all researchers in an equitable and timely manner. This requires a concerted effort throughout the NHS and consistent demand as well as financial

support from researchers, particularly within industry. It is our view that the next 5–10 years will generate compelling evidence of the value of functional human tissue-based tests and recognition that more efficient use of residual or non-transplantable tissues and organs is an urgent priority for the development of new medicines.

**Keywords** Surgical tissues · Transplant · Drug safety · Pharmacodynamics · Pharmacokinetics

If functional human tissues offer such promise, it is reasonable to ask whether sufficient human tissue is available to make a significant contribution to drug development. In England and Wales, upwards of 600,000 residual surgical tissues are generated each year, yet only a tiny fraction is made available to researchers.

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# Human lung tissue engineering: a critical tool for safer medicines

Kelly BéruBé · Claire Gibson · Claire Job · Zoë Prytherch

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**Abstract** In the field of human tissue-engineering, there has been a strong focus on the clinical aspects of the technology, i.e. repair, replace and enhance a given tissue/organ. However, much wider applications for tissue engineering (TE) exist outside of the clinic that are often not recognised, and include engineering more relevant models than animals in basic research and safety testing. Traditionally, research is initially conducted on animals or cell lines, both of which have their limitations. With regard to cell lines, they are usually transformed to enable indefinite proliferation. These immortalised cell lines provide the researcher with an almost limitless source of material. However, the pertinence of the data produced is now under scrutiny, with the suggestion that some historical cell lines may not be the cell type originally reported. By engineering normal, biomimetic (i.e. life-mimicking), human tissues with defined physiology (i.e. human tissue equivalents), the complex 3-dimensional (3-D) tissue/organ physiology is captured *in vitro*, providing the opportunity to directly replace the use of animals in research/testing with more relevant systems. Therefore, it is imperative that testing strategies using organotypic models are developed that can address the limitations of current animal and cellular models and thus improve drug development, enabling faster

delivery of drugs which are safer, more effective and have fewer side effects in humans.

**Keywords** Tissue engineering · Lung · Organotypic models · Safety testing

To discover a new drug, many compounds must be screened and evaluated for efficacy and toxicity, and much of that testing occurs outside the species of interest, in animals or in their tissues. The ensuing extrapolation of results to humans is fraught with difficulty, especially given that individual people can react differently to the same drug.

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# The use of human tissue in drug discovery

Iain G. Dougall

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**Abstract** Experiments conducted on human tissue samples are a key component of modern drug discovery programs and complement the use of animal tissue based assays in this process. Such studies can (i) enhance our understanding of disease pathophysiology, (ii) increase (or decrease) confidence that modulating the function of particular molecular targets will have therapeutic benefit (iii) allow comparison of the activities of different agents on particular mechanisms/processes and (iv) provide information on the potential safety risks associated with targets. All of this information is critical in identifying the targets that are most likely to deliver efficacious and safe medicines to address unmet clinical needs. With the introduction of new technologies, human tissue samples are also increasingly being incorporated into drug project screening cascades, including their use in high throughput assays. Improved access to human tissue would undoubtedly further extend the utility of this valuable resource in the drug discovery process.

**Keywords** Lung tissue · Drug safety · Target validation

The aim of drug research is to identify new medicines that will provide efficacious and safe treatments for human diseases. To that end, a range of biological assays and techniques are employed throughout the drug discovery process. Increasingly central to this task is the use of human tissue, which provides an invaluable and obvious link to the clinic.

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# Pathology: coming in from the cold

Christopher S. Foster

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**Abstract** Following the UK's organ retention scandals that occurred a decade ago, politicians unleashed a deluge of well-intentioned but naïve and unnecessarily burdensome regulations that have progressively stymied human tissue-based research, stifling development of improved diagnostic and prognostic tests as well as discovery of new treatments based on sound knowledge of human-specific biology. For the UK to maintain a leading role in medical research, more sensible levels of regulation need to be introduced that recognise differences between tissue from donors who have passed-away and surgical tissue that is surplus to diagnostic requirements and that otherwise will be incinerated. While it is important to reassure the public that research using their tissues will be conducted within an approved ethical framework, it is equally important to ensure that, as hospital staff and academic researchers, we are able to fulfil our unwritten covenant with patients to do our utmost to seek better diagnostic assays and more predictive prognostic indicators, while collaborating with our colleagues in academia and industry and hence bring hope to patients with illnesses for which no effective treatments are yet available. There is a clear case for introducing an opt-out system as the default to allow all surplus surgical tissues to be

immediately available for research, concomitant with an education campaign. This is the optimal and most ethical approach to ensure the wishes of the vast majority of patients are respected by allowing their residual surgical tissues and relevant clinical information to be made available for research without the current levels of obstruction and hindrance.

**Keywords** Pathology · Animal models · Consent · Funding · Human Tissue Act · Translational research · UK GDP

Working as a clinician, scientist and translational pathologist, it is clear that we should be seeking to develop the best evidence, methods, approaches and therapies that are most appropriate for the human species (*Homo sapiens*). No longer should we extrapolate data from rodents or lagomorphs and expect that data derived from the use of such animals might be an exact biological model of human diseases or therapies.

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# Ethical tissue: a not-for-profit model for human tissue supply

Kevin Adams · Sandie Martin

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**Abstract** Following legislative changes in 2004 and the establishment of the Human Tissue Authority, access to human tissues for biomedical research became a more onerous and tightly regulated process. Ethical Tissue was established to meet the growing demand for human tissues, using a process that provided ease of access by researchers whilst maintaining the highest ethical and regulatory standards. The establishment of a licensed research tissue bank entailed several key criteria covering ethical, legal, financial and logistical issues being met. A wide range of stakeholders, including the HTA, University of Bradford, flagged LREC, hospital trusts and clinical groups were also integral to the process.

**Keywords** Ethics · Licensing · UK national health service · Human tissue act

responsibility to ensure that any research carried out within their walls conforms to the requirements of the Act, as administered by the Human Tissue Authority (HTA). Equally, academic or industrial researchers are under considerable pressure to change habits with the need to conform to the requirements of the HTA.

The Human Tissue Act of 2004 has changed the way in which researchers can access, work with and ultimately dispose of human tissues. Institutes, be they academic or commercial, now have a legal

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# Linking organ donors and the medical/scientific research community: a US perspective

Dolores Baldasare

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**Abstract** The International Institute for the Advancement of Medicine (IIAM) provides non-transplantable organs and tissues for medical and scientific research, education, and drug & device development. The benefits of using human organs and tissues for research are vast, and donating for research provides donor families with a valuable option if their loved one's organs are unsuitable for transplantation. The use of these organs and tissues enables the faster development of more efficacious drugs with improved safety profiles, and enhanced understanding of basic disease processes that directly affect humans. Human organs and tissues offer unique advantages over the use of animal organs and tissues as it is human diseases and conditions which we seek to treat, and so logically the results can be more directly applied. The added advantage of accessing non-transplantable, human organs is that they are in superb condition, and so experiments can be conducted in a very physiologically-relevant system. Although the US is a sizeable country with a large population and individual regulations governing human tissue collection and usage for each of the 50 states comprising the US this article will discuss how IIAM succeeds in

immediately linking organ donors and qualified researchers, ultimately to the great benefit of patients.

**Keywords** Non-transplantable organs · Consent · Medical research · Organ and tissue donation

Invaluable information leading to the prevention of, and cures for, human diseases has been uncovered through the study of human organs and tissues for research while at the same time saving an infinite amount of time, effort, money and risk on unsuccessful trials with animals.

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# The current limitations on tissue banking from an academic perspective

Barbara K. Pierscionek

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**Abstract** For research on human physiology and pathologies the most relevant results come from human tissue, necessitating the creation of more tissue banks. This need is acknowledged by academics, clinical researchers and the pharmaceutical industry. For academics, the major obstacles to establishing tissue banks are the somewhat cumbersome ethical procedures, a perceived lack of demand for human tissue and insufficient knowledge about supply and its demographic differences. The causes are inter-related: confusing and time-consuming ethics applications cause some researchers to avoid human tissue work and expend research efforts on animal studies, leading to a false presumption of a lower level of demand for human tissue. Lack of knowledge about why rates of donation are low, and why there are differences in donation for different organs, leads to an uncertainty about supply. This too poses a problem for tissue bank establishment, and further research into this area is required.

**Keywords** Ethics · Rates of donation · Demand · Demographics · Population attitudes

As the technology that underpins scientific and clinical research improves, the need for human cells, tissues and organs to produce results that are viable and applicable to human conditions and diseases is receiving greater recognition. Yet obstacles to establishing cell, tissue and organ banks remain. Such tissue banks need a tripartite approach with partners from academia, hospitals and the pharmaceutical industry working together.

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# Access to organs and tissues for research from the organ donor pool within the UK

Barry J. Fuller

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**Abstract** The donor organ transplant scenario offers one potential route to access high-quality human organs and tissues for research. There are well-established networks for co-ordinating organ donation events across many countries, including the UK, which include robust mechanisms for obtaining consent for ethically-approved research. Within the UK, the challenge for the next few years is to facilitate this research donation with respect to regulatory pathways directed by the Human Tissue Act, which covers all aspects of access to human tissues.

**Keywords** Non-transplantable organs · Human Tissue Act · *Post-mortem* tissues · Hypoxia

Access to human organs for research remains a major issue to be addressed in the coming decade. A host of societal and ethical questions surround this topic, but the importance of human tissues of high functional quality to maximise the benefits available from modern molecular and genetic technologies is extremely high. Broadly, the general public are very

supportive of the research necessary to improve the safety and efficacy of medicines and to develop new therapies, whilst being increasingly wary of the need for, and relevance of, animals in research- concerns shared by many professional scientists and regulatory bodies.

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# Tissue banking for research—bench to bedside and back—myth, reality or fast fading reality at the dawn of a personalised healthcare era

Anup Patel

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**Abstract** In this article, the current landscape where bio-resource based research underpins a future paradigm of personalised healthcare is explored and important issues are highlighted. Barriers, challenges and needs are described and suggest a need for restructuring, resourcing and investment to increase user-friendliness in the clinical setting for future gains, while safeguarding the patient.

**Keywords** Surgical tissues · Personalised medicine · Consent · Pathology

infant mortality and life expectancy. These advances would not have been possible without being underpinned by high quality basic science laboratory research. The practice of medicine continues to evolve in the modern era at an exponentially faster rate through advances in technological science underpinned by greater computing speed, and progress in molecular scientific disciplines such as genomics and proteomics.

Arguably, the greatest medical advances of the past century were the introduction of effective immunisation and antibiotics. Coupled with clean water supplies and sanitation, they vastly reduced the impact of infectious diseases (viral and bacterial) at a global level, once and for always changing both

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# Tissue banking for research: connecting the disconnected

Geraldine Thomas

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**Abstract** Delivering the promise of personalised medicine is the challenge that the current generation of scientists face. The variations in human physiology and disease are considerable, and designing appropriate strategies to deliver what has been promised will require access to tissue from a large number of volunteers. The NHS provides an ideal infrastructure for sample acquisition, but requires two things to make this available—public consent and support for extra manpower and administration. There is a disconnection between the NHS and tissue based research that needs to be addressed on a number of levels to provide a translational platform. This should enable the path to be beaten to provide the ideal tailored treatment for future patients; one that preserves quality of life by curing the disease with minimal side effects.

**Keywords** Animal models · Pathology · Personalised medicine · NHS · Infrastructure

## Man or mouse?

High quality research that will benefit patients requires research to be done in an appropriate model. In the clinic, we treat patients, and therefore the most appropriate model is the human. The vast majority of the public accepts this, and when asked for their consent to use material taken from their own bodies as part of a treatment or investigation, patients' response is positive. For too long we have used animal models for human disease. These can be beneficial for investigating specific hypotheses in disease development and for gaining basic safety data, but in the end we must rely on our own species for proof of efficacy. If we understood better what makes our own bodies tick and what becomes deranged in disease we would have a better chance of tailoring treatment for humans, rather than for mice.

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# TESTING CONDITIONS



**Medical research**  
Human tissues are invaluable for medical research, and we should work to make them more available, says **Lord McColl of Dulwich**

**T**he pressing need for human tissues and organs for transplant has, quite rightly, received much attention.

A related issue, and one which has received relatively little emphasis, is the vital role that tissues and organs removed during surgery, or which cannot be used for transplant, play in the research process responsible for delivering new medicines.

Before any new medicine can be tried in patients, it must undergo extensive testing. Today, much of that testing occurs outside the species of interest, in animals or in their tissues. Extrapolating results from laboratory animals to people has always been fraught with difficulty: even individual people can react very differently to the same drug.

The more detailed knowledge we acquire about the molecular basis for the workings of the human body, and the differences between species commonly used in the laboratory, the more obvious it becomes that we cannot continue to rely on animals to model humans.

This is particularly pertinent when we consider the vast array of new technologies based on human biology that are now available to test new drugs. The value of using human tissues from every organ in the body in this process is increasingly recognised, and an increased supply of tissues will be necessary to facilitate better research in the future.

There is wide agreement amongst professionals and the

public that tissue donation for research is worthwhile, but little agreement on who should be responsible for ensuring that surplus tissues which are currently incinerated are put to good use, or how to bring that about.

A decade after the organ-retention scandal at Alder Hey broke, perhaps it is time to reassess the effect that that scandal had on public trust in scientists, and how the regulations, and the understanding of those regulations, introduced in its wake, have impacted upon this area of research.

A conference has been arranged this week (Tuesday October 20, 12.30-3.30pm Committee Room G, House of Lords; followed by afternoon tea, an open Q&A and a discussion session in the Attlee Room, House of Lords until 5pm) to bring together my fellow surgeons, pathologists, patient safety representatives, regulators such as the Human Tissue Authority, and researchers from academia and industry.

Our aim is to find a way forward to ensure that medical researchers have an ethical and reliable source of materials to carry out their vital work.

The Safety of Medicines (Evaluation) Bill seeks to address the broader issue of which technologies are best placed to address the needs of regulatory safety testing today. After the thalidomide disaster, animal testing of new drugs before they could be trialled in patients was made mandatory.

This bill seeks a comparison between those tests and a battery of the newer, human biology-based tests that were simply not available at that time.

EDM 569 in support of this bill has received 211 signatures to date, indicating the significance of this issue and its broad relevance, addressing as it does the safety of products which

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**The more detailed knowledge we acquire about the molecular basis for the workings of the human body, the more obvious it becomes that we cannot continue to rely on animals to model humans**

probably all of us rely on at some stage in our lives. If these newer methods are to be adopted, better access to waste human tissues will be required, and the infrastructure must be in place to support this.

I urge you to drop in on October 20 to hear some of the speakers, who have come from all over the UK and the US. ●

**Professor the Lord McColl of Dulwich is a Conservative health spokesman**



# the answer is in tissue

View the eye-opening presentations from October's **Human Tissues Conference** in the House of Lords, or register your interest in the new Working Party on Human Tissues at: [www.safermedicines.org/humantissues](http://www.safermedicines.org/humantissues)

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The Human Tissue Act (2004) has placed a stranglehold on UK Academic Medicine, particularly Academic Pathology. Legitimate access to human tissues has become restricted with the result that essential biomedical research into human diseases has been compromised. The pharmaceutical industry, a major contributor to the UK economy, is also suffering from the recent restrictions.

Reduced access to human tissues, especially those that are otherwise discarded following surgical procedures, undermines a tacit expectation by all members of society that doctors and scientists within the UK are working to solve biomedical problems and discover new treatments so that each person might receive the most appropriate care when they become ill. In many respects, this unwritten contract between the public and the biomedical research community has been jeopardised by the Human Tissue Act.

There is now sufficient objective evidence that application of the Human Tissue Act in its present form is compromising aspects of scientific endeavour within the UK and needs urgent revision. It is vital that tissue samples that are redundant after diagnostic requirements should be made more freely available for ethical biomedical research for the benefit of all members of society.

Professor Christopher S. Foster

Dr Margaret Clotworthy

Lord McColl of Dulwich

Baroness Finlay of Llandaff

Professor Sir Nicholas A. Wright

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