

## The Human Tissue Bill

After the deep distress of Alder Hey and Bristol, and the Body Works exhibition, the requirement for regulation over human tissues after death is clear. But regulation must balance consent with the duty to ensure the cause of death has been accurately ascertained and any future additional important information remains available from tissue blocks and slides. The danger is that this Bill covers both post-mortem and surgically removed specimens. Histology is essential for accurate diagnosis (e.g. a normal-looking heart can reveal widespread myocarditis on histology) and relatives want to be certain that organs have been returned to the body, but what of the parts of organs taken to prepare blocks and from these finely sliced sections for slides?

Such tissue blocks and slides, currently retained in pathology departments' archives, can provide more information on the cause of death, effects of treatment, for public health surveillance and to monitor infections such as variant CJD. Archived material can be very important, sometimes years later for the individual family and for society at large. When a new gene locus is identified, the genetic disorders can be investigated and other affected family members identified, including possible pre-natal diagnosis. Questions about the circumstances or human culpability around a death, rather than the natural cause alone, require the capacity to revisit blocks and slides, to allow appeals in the light of new knowledge. It must be possible to review a case beyond the time of apparent completion of the process in law. The risk of miscarriage of justice - both wrongful and failed conviction and the impact on wider public safety - cannot be ignored.

Specimens from surgically removed tumours form the basis of future research; the resources are not available to trace every patient whose discarded tumour is important. No one can predict issues of future importance. A new cell-surface receptor may indicate why some patients respond well to treatment and others fare badly, or simplify diagnosis. Helicobacter was discovered to cause peptic ulceration because an enquiring pathologist noticed wiggly shapes on the slides, dug out archived specimens and found that the 'artefacts' were present in the areas of ulcer inflammation; the treatment of peptic ulcer has been revolutionised. Careful review of archived rectal tumour surgical specimens showed the importance of tumour-free margins to avoid recurrence, resulting in new improved surgical resection techniques. Without unselected archiving, such discoveries may have been delayed by years. There is no evidence that patients actually want to stop such groundbreaking research happening.

If explicit consent has to be obtained for post-diagnosis block and slide retention and subsequent use, then the specimens will not be there for research, education and training, nor for routine quality assurance, audit and public health monitoring. Histology requires a normal control and a disease specimen for comparison; with rare conditions, the archived material comes into its own.

Blocks and slides are essential for education and training purposes. Explicit consent will be required for specimens to be used for education and training of the next generation of histopathologists. There are no new resources to trace the relatives or patient to obtain consent. The current shortage of pathologists is set to continue; it seems a poor use of histopathology time trying to contact those who may have moved away and for whom the specimen has no relevance.

When surgical and post-mortem consent is obtained, the form should incorporate consent for use of specimens for future education, training and research unless the patient decides to opt out of this. The Bill must balance consent and the responsibility to further knowledge for the wider good.

**Baroness Finlay of Llandaff on behalf of the Council for Heads of Medical Schools**