I. INTRODUCTION AND BACKGROUND

The Human Tissue Act 2004 (hereafter the 2004 Act), which (inter alia) consolidated the law on organ donation and repealed earlier legislation, came into effect in England, Wales, and Northern Ireland on 1 September 2006.¹ The Human Tissue Authority...
(HTA), the regulatory body established by the 2004 Act, and the NHS Blood and Transplant Organ Donation and Transplantation Directorate (NHSBT ODT), formerly known as UK Transplant (UKT), the national organ allocation body, continue to follow a long-established policy of accepting deceased donor organ donations only on an undirected, or ‘unconditional’ basis. The ‘central principle’ of organ allocation from deceased donors is that they must go to the person who is most in need and has the best match with the donor—a donor can neither direct the organ to a specific recipient nor impose conditions as to who shall be chosen; all such restrictions may be ignored as invalid.

This policy did not come into being with the 2004 Act, but had already been generally adhered to in the case of deceased organ donations, since about the time of the Human Tissue Act 1961 (repealed by the 2004 Act). Although it does not appear to have been clearly expressed until relatively recently, it has been widely applied, with almost universal support of organ donation and transplant centres (at least as far as the exchange of organs between centres is concerned) and is usually regarded as legally binding.

The ethical basis underpinning deceased organ donation allocation is one of impartial justice. It is in this context that issues of fairness and efficiency in allocation arise. Some have remarked that organs are public resources to be distributed by relevant agencies on behalf of the state. Consequentialists, who believe that an action should

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2 The HTA was set up under the Human Tissue Act 2004. It is charged with regulating the removal, storage, use, and disposal of human bodies, organs, and tissue from the living and deceased (excluding gametes and embryos).

3 The NHS Blood and Transplant (NHSBT, www.nhsbt.nhs.org) Organ Donation and Transplant Directorate (NHSBT ODT) is now the body responsible for deceased donor organ allocation in the UK. It replaced UK Transplant (UKT, www.uktransplant.org.uk), the body formerly responsible for deceased donor organ allocation in the UK, in 2009.

4 Human Tissue Authority statement on directed donation of organs after death. Issue date 14 April 2008.

5 Conditional donation is when a donor organ (or organs) is (are) offered to (or possibly withheld from) a specific class of recipient. Directed donation is when a donor organ (or organs) is (are) directed to a specific person, or a nominated individual is given priority. For a recent definition, distinction, and ethical discussion, see ML Volk and PA Ubel, ‘A Gift of Life: Ethical and Practical Problems with Conditional and Directed Donation’ (2008) 85(11) Transplantation 1542–1544.

6 Report of the Panel, An Investigation into Conditional Organ Donation (Department of Health 2000). The inquiry conclusions are outlined in L Beecham, ‘Donors and Relatives Must Place No Conditions on Organ Use’ (2000) 320 BMJ 534.

7 For a discussion, see AJ Cronin and D Price, ‘Directed Organ Donation: Is the Donor the Owner?’ (2008) 3 Clinical Ethics 127–131.

8 See e.g. Report of the Task Force on Organ Transplantation, Department of Health & Human Services, 1986, p 77 and Congress Resolution 8 in
be judged in terms of the consequences that follow from it, and will support whatever action has the greatest benefit for the greatest number, may provide us with good and prudential reasons for supporting a system of organ donation in which organs from the deceased are considered public goods automatically available for transplantation, directly imported into an impartial equitable system of organ allocation. Any refusal to donate costs lives and it is undoubtedly the case that thousands of individuals have needlessly died an untimely death waiting for a transplant. But if we endorse the consequentialist position and consider that deceased donor organs are a public resource or community ‘property’ to be allocated according to agreed jurisdictional policies, then we must be able to provide an explanation as to from where such dispositional authority and property rights are derived. Moreover, the concept of human body parts as property requires a consideration of what this may imply for individual donor ownership, as well as for both directed and conditional donation.

In marked contrast, the rationale underpinning living organ donation is donor autonomy and respect for an individual’s wishes and informed decision. At their outset, living donor transplant programmes emphasised specifically directed donation. An individual was entitled to donate to another individual in whom he, or she, had a special interest, a brother say. Kluge, for instance, argued that donations by living persons ‘create and sustain intimate personal relationships’ and, in particular, family ties, and constitute exceptions to the general rules of impartial allocation. Non-directed donation was to some extent mistrusted as it did not involve the personal bond considered necessary to overcome the reluctance of doctors to inflict surgical injury on one person for the benefit of another. As late as 1986, the UK medical opinion regarded all living donation as justifiable only in exceptional circumstances. However, the increasingly good outcome of living donor transplantation, not only to close genetic relatives but

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9 See generally J Glover (ed), Utilitarianism and Its Critics (Macmillan, London, 1990).
10 J Harris, ‘Organ Procurement: Dead Interests, Living Needs: Cadaver Organs Should Be Automatically Available’ (2003) 29 JME 130–134.
11 Harris (n 10). See also AJ Cronin, ‘Equitable Access to Organs’ in W Weimar, MA Bos, JJ Busschbach (eds), The Ethical, Legal and Psychological Aspects of Organ Transplantation (Pabst Publishers, Lengerich, 2008) 99–110.
12 Cronin and Price (n 7).
13 EH Kluge, ‘Designated Organ Donation: Private Choice in Social Context’ (1989) 19 Hastings Center Report 10.
14 RA Sells, RWG Johnson and J Hutchinson, ‘Recommendations on the Use of Living Donors in the UK’ (1986) 293 BMJ 257–258.
also to unrelated recipients, combined with the ever-increasing demand for organs, made living donor organ transplantation an altogether more attractive model and enhanced its ethical acceptability. In the UK, it remains the case that most living donations are directed. They usually involve a healthy person donating an organ (often a kidney) or part organ (for example, the liver or lung lobe) to a specific recipient who is related to the donor either genetically or emotionally. Although now regulated by section 33 of the 2004 Act, directed donations between close family members, including spouses, are always lawful, provided that the HTA is satisfied that no element of reward or coercion exists—they currently account for over one-third of all annual kidney transplants.

Thus, so it seems, two parallel donation/allocation regimes have evolved and are in operation with (in essence) an impartial justice rationale governing deceased donation and a partial autonomy-driven rationale underpinning living donation. This is reflected in other jurisdictions. The overall picture, however, is less straightforward than it

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15 PI Terasaki and others, ‘High Survival Rates of Kidney Transplants from Spousal and Living Unrelated Donors’ (1995) 333 NEJM 333–336.

16 The requirements for living donor transplantation are set out in the 2004 Act s 33–34 and in the Human Tissue Act 2004 (Persons who Lack Capacity to Consent and Transplants) Regulations 2006 ss 9–14 These regulations are detailed at <www.opsi.gov.uk/si/si2006/20061659.htm>. The Human Tissue Act 2004, Revised Code of Practice 2 ‘Donation of Solid Organs for Transplantation’ (September 2009) Section para 26 outlines the types of living organ donation that may take place. <http://www.hta.gov.uk/legislationpoliciesandcodesofpractice/codesofpractice/code2donationoforgans.cfm?FaArea1=customwidgets.content_view_1&cit_id=673&cit_parent_cit_id=669>. In 2008–2009, out of a total of 927 live kidney donations, 16 were paired or pooled and 15 altruistic non-directed. See Transplant Activity in the UK, 2008–2009 Table 3.1. See the NHSBT and UKT Transplant Report 2009. <www.organdonation.nhs.uk/ukt/statistics/transplant_activity_report/current_activity_reports/ukt/transplant_activity_uk_2008-2009.pdf>.

17 A genetically related donation is one in which the potential donor is a blood relative of the potential recipient. An emotionally related donation is one in which the potential donor has a personal relationship with the potential recipient, for example, spouse, partner, or close friend.

18 Transplant Activity in the UK, 2008–2009, Table 3.1. See the NHSBT and UKT Transplant Report 2009. <www.organdonation.nhs.uk/ukt/statistics/transplant_activity_report/current_activity_reports/ukt/transplant_activity_uk_2008-2009.pdf>.

19 D Price, ‘Legal Systems for Organ Distribution in Europe: Justice in Allocation’ in W Weimar, MA Bos, JJ Busschbach (eds), The Ethical, Legal and Psychological Aspects of Organ Transplantation (Pabst Publishers, Lengerich, 2008) 163–174. See for example, the applicable laws in Poland and the Czech Republic, and the evolution of policies of the relevant national and supranational organ allocation agencies. See also Council of Europe Additional Protocol to the Convention on Human Rights and Biomedicine, on Transplantation of Organs and Tissues of Human Origin, 2002, Strasbourg, Article 3.
might at first appear. Anonymous ‘altruistic’ donation\textsuperscript{20} is permitted by strangers in the UK under the 2004 Act, subject to HTA approval. Under the established scheme, such donations are not allowed to be directed. Rather, organs are allocated to the most suitable candidate waiting on the national transplant list. The absence of any pre-existing relationship and ‘spillover’ into the province of the deceased donor allocation scheme apparently requires that the principle of impartial justice and equity govern the distribution rather than the dispositional powers of individual donors.\textsuperscript{21} ‘Paired’ and ‘pooled’ donations\textsuperscript{22} are also permitted, subject to HTA approval. In this instance, donors and recipients are arranged in pairs or pools and placed in a ‘matching run’.\textsuperscript{23} Paired or pooled donor organs (usually kidneys) are then allocated or ‘swapped’ between them in such a way as to maximise the tissue compatibility (and therefore also outcome). In paired and pooled donation, the exchanging pairs are not required to be mutually acquainted. In fact, in most (if not all) cases of paired or pooled exchange, the transplant recipient is unknown to the donor.

Both non-directed altruistic and paired living donor transplants were first developed in the USA as a means of increasing the availability of donor organs for transplantation\textsuperscript{24} and of overcoming the inability of

\begin{footnotesize}
\begin{enumerate}
\item A living person who has never met the possible recipient may become an organ donor. According to NHSBT transplant activity reports, between July 2007 and March 2009 there were twenty-one non-directed altruistic living donor transplants.\textsuperscript{20}
\item Cronin and Price (n 7).
\item Paired donation and transplantation is possible when a potential donor is unable to donate directly to his/her relative, spouse, or friend, but can donate to an unknown person (also a potential transplant recipient) whose relative, spouse, or friend can, in exchange, donate to the original patient. In paired exchange, then, an incompatible living donor and recipient ‘pair’ can ‘swap’ organs with another ‘pair’ in the same situation. If more than two living donors and two recipients are involved in the swap and more than one exchange takes place, it is called ‘pooled donation’. See also The Human Tissue Act 2004 (Persons who Lack Capacity to Consent and Transplants) Regulations 2006 SI 2006 No. 1659 and the Human Tissue Authority Code of Practice 2, Donation of Solid Organs for Transplantation, 2009, at paras 26.
\item A ‘matching run’ refers to a series of tests performed to identify tissue compatibility between organ donors and potential transplant recipients. In the UK, ‘matching runs’ are currently performed 3 monthly; however, matching runs will be carried out at intervals determined by the rate at which incompatible couples join the paired donation list. For further details, see <http://www.uktransplant.org.uk/ukt/about_transplants/organ_allocation/kidney_(renal)/living_donation/paired_donation_matching_scheme.jsp>.
\item A Matas and others, ‘Non-directed Donation of Kidneys from Living Donors’ (2000) 343 NEJM 433–436.
\end{enumerate}
\end{footnotesize}
a potential living donor to donate a kidney to a specified recipient (e.g. a spouse), due to the presence of tissue incompatibility. 25 Non-directed altruistic and paired living donor transplants were first performed in the UK by virtue of section 33(3) of the 2004 Act. By regulations made under it, this section’s general restriction of living donation does not apply where the HTA is satisfied (i) that no reward has been, or is to be, given and (ii) that other conditions specified in the regulations are satisfied—none of which prohibit paired or altruistic non-directed donations. It has been claimed that the 2004 Act changed the law to allow these advances in donation. 26 But, in our opinion, they would have been equally possible under the Human Organ Transplant Act 1989 (hereafter the HOT Act), which first restricted living donation. Its text was almost identical to that of the 2004 Act and contained nothing either in the main statute 27 or in its regulations to prevent them; only payment and coercion were specifically forbidden. 28 Nevertheless, during the 17 years of the HOT Act, the Unrelated Live Transplants Regulatory Authority (ULTRA), the HTA’s predecessor, discouraged applications for any of these non-directed donations. This was criticised, 29 but not challenged. In retrospect, we consider that ULTRA underestimated and failed to exercise its authority in this respect 30 and thus acted as a brake on a relatively small 31 but, for individual patients, important advance in clinical transplantation. 32

In considering the ethical principles which in practice are applied by the regulatory authority to both deceased and living donor transplantation, and highlighting ‘non-directed altruistic’, and paired or pooled living donor transplant schemes, we can see that there is incongruity in the current position. For, so it seems, the situation is as follows. Although we are allowed to decide for ourselves whether or not we

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25 FL Delmonico, ‘Exchanging Kidneys: Advances in Living Donor Transplantation’ (2004) 350 NEJM 1812.
26 AR Weale and PA Lear, ‘Organ Transplantation and the Human Tissue Act – Changes in the Law May Have a Positive Impact on Organ Donation’ (2007) 83 Postgrad Med J 141–142. The authors comment: (a) ‘the Act provides a framework by which (paired transplants) can occur both legally and ethically’; and (b) ‘Non-directed donation will be made legal by the Act’.
27 Human Organ Transplant Act 1989 s 2(3).
28 Human Organ Transplant (Unrelated Persons) Regulations 1989 s 3 (Statutory Instrument 1989 SI No. 2480).
29 S Chowdhry and others, ‘Unrelated Living Organ Donation: ULTRA Needs to Go’ (2003) 29 JME 169–170.
30 This could have been examined by judicial review.
31 WH Marks and others, ‘Organ Donation and Utilization, 1995–2004: Entering the Collaborative Era’ (2006) 6 Am J Transplant 1101–1110. In 2004, 88 out of 2343 living unrelated donors in the USA were non-directed.
32 The Human Tissue Act 2004 s 33(4) does provide for a mechanism for ‘reconsideration’ of the HTA’s decisions with respect to living donation.
want to be organ donors upon our death, in the event that we do, we
cannot attach any condition to our ‘gift’ to society or specify a particular
recipient, even if this is a person with whom we have a personal relation-
ship. Instead, somehow or another, our donation slips straight into the
net of public resource and impartial allocation. Nevertheless, once our
consent is established, the donation can proceed without further regu-
lation. If, on the other hand, we are alive when we donate, we may
then legitimately direct our donation (our gift) to a specified person
with whom we do hold a relationship of some kind or another. In
fact, provided our living donation occurs in the context of a relationship,
we can even have our donation directed on our behalf to a stranger and
in return we will reap the benefit of seeing the person with whom we
have a relationship receive a similar reciprocal gift. If, however, our
living donation is not in the context of a pre-existing relationship of
some kind or another, we cannot legitimately direct the very same
donation (or gift) to a specified stranger, but must instead make an
unconditional donation.33 Furthermore, regardless of whether living
donations are directed or non-directed, living donor consent, though
necessary, is not sufficient to ensure donation but (unlike the consent
of an individual who wishes to become a deceased donor) must first
pass the scrutiny of the regulatory body (the HTA). Can we really con-
sider that there are two allocation schemes working in parallel when the
outcomes can be so incongruous?34

Directed and conditional donations challenge the traditional model of
deceased donor organ allocation based on equity and impartial justice in
a powerful and striking way.35 We might agree that allowing for such
restrictions will inevitably compromise the principle that organs from
deceased donors should be distributed according to a system of impar-
tial justice and equity, with an emphasis upon those with the greatest
medical need, in specific instances. But if we continue to accede to a
model of ‘appropriate consent’36 or ‘authorisation’,37 both afforded
primacy in the 2004 Act and the Human Tissue (Scotland) Act 2006
respectively, as the basis upon which deceased donor organs become
available for transplantation, then we must provide good reason as to

33 Cronin and Price (n 7).
34 Ibid.
35 Ibid.
36 The law protects individuals’ rights to control the use of their bodies for
medical purposes. See generally J Herring, ‘Crimes Against the Dead’ in B
Brooks-Gordon and others (eds), Death Rites and Rights (Hart Publishing,
Oxford, 2007) 219–239. It is by virtue of this right that the Human Tissue
Act 2004 empowers an individual to appropriately say ‘yes’ or ‘no’ to
(consent or refuse) organ donation. See Human Tissue Act 2004, s 3.
37 Ibid. The Human Tissue (Scotland) Act 2006 uses the term ‘authorisation’.
why such authorisation does not allow for the possibility of individual deceased donors placing restrictions or conditions upon such authorisation before their death. In particular, if the context of a relationship merits such importance and, as would appear to be the case, gives legitimacy to the directedness of one’s donation, why should deceased donations, to family members say, not also be acceptable?

Both unrelated and related living donors have lost some of their former autonomy, as all living donations now require prior authorisation by a statutory body (the HTA) to exclude the presence of reward or coercion.\(^{38}\) This was largely brought about following the unexpected and unwelcome emergence of organ trafficking,\(^{39}\) despite being banned in the UK since 1989.\(^{40}\) In the case of deceased donation, the 2004 Act now requires that ‘appropriate consent’ must be established in all cases of organ removal for transplantation,\(^{41}\) rather than the mere absence of objection which sufficed to confirm legality under earlier legislation.\(^{42}\) In effect, therefore, both living and deceased donation now always require the oversight of a statutory body. The advantage of statutory regulatory authorities is that they ensure uniform donation practice throughout the country, and to some extent facilitate it. The disadvantage is that these authorities, especially if they have the power to disallow donations, either by law or in practice, may, if unchallenged in the courts, misinterpret the law by applying their own ethical concepts beyond the limits which the law allows. In this paper, we contend that the acceptance of the ‘central principle’ of unconditional deceased donor organ donation as legally binding, or close to legally binding, rather than as an operational policy, is just such a misinterpretation, and seek to demonstrate not only that directed and conditional deceased donor organ donations are not illegal \textit{per se}, but also that to overrule an individual’s request (or attempt to place a condition upon a donation) may conflict in law with the principle of ‘appropriate consent’ considered by many to be the central fundamental tenet and ‘golden thread’ of the 2004 Act. Moreover, we suggest that allocating organs as though they were donated without restriction may carry a risk of criminal liability for local transplant teams.

\(^{38}\) Human Tissue Act 2004 s 33.
\(^{39}\) In the UK, Dr Raymond Crockett was struck off the medical register by the General Medical Council in May 1990. He was found guilty of procuring human organs from living donors in exchange for money, as part of a ‘kidneys for sale’ scam. Organs from four Turkish patients were transplanted into private patients at the Wellington Humana Hospital in St John’s Wood, London. \langle\texttt{http://news.bbc.co.uk/1/hi/health/937204.stm}\rangle.
\(^{40}\) Human Organ Transplants (HOT) Act 1989 s 1; now replaced by the Human Tissue Act 2004 s 32.
\(^{41}\) Human Tissue Act 2004 s 3.
\(^{42}\) Human Tissue Act 1961 s 1(2)(a).
NHSBT ODT, and even the HTA itself. Although the HTA is free to pursue an unconditional policy for the acceptance of organs through ODT, this body has no enforceable ‘monopoly’\textsuperscript{43} over deceased organ donation.\textsuperscript{44} Thus, so it seems, both directed and conditional deceased donor organ donations may lawfully be performed without its participation, provided that they comply with the 2004 Act and are not illegal for any other reason.

The clash between individual authorisation and public benefit was brought to the fore in the ‘Ashworth Affair’ of 2008, which thus forms a useful starting point for an analysis of the relationship between underlying ethical principles, regulatory policy, and the actual law of organ donation.

**II. THE ASHWORTH AFFAIR**

In April 2008, press reports of an attempted directed deceased donor organ donation between close relations led to controversy.\textsuperscript{45} The donor, Laura Ashworth, a 21-year-old woman, had allegedly wished to donate one of her kidneys to her mother, Rachel Leake, who had end-stage renal failure and was at that time on haemodialysis. However, at the time of her death, she had not begun the formal process of becoming a ‘living donor’. UKT\textsuperscript{46} referred the matter to the HTA whose response (in an official statement explaining its decision) was unequivocal:

> The central principle of matching and allocating organs from the deceased, it stated, ‘is that they are allocated to the person on the waiting list who is most in need and who is the best matched with the donor. This is regardless of gender, race, religion or any other factor.’\textsuperscript{47}

The inflexibility of such a policy has been criticised, for reasons which became clear in this case.\textsuperscript{48} If Laura had gone through the formal process of living donation and still been alive, the HTA would have considered it legitimate for her to direct the donation of one of her kidneys to her mother subject to its approval, which there would have been no

\textsuperscript{43} In contrast with most other scheduled activities under the 2004 Act, no licence is required to remove material for transplantation. In contrast with medium to longer term therapeutic tissue banking, no licence is required for storage of organs for transplantation either.

\textsuperscript{44} This is in contrast to its counterpart in the USA. The Organ Procurement Transplant Network (OPTN).

\textsuperscript{45} <http://news.bbc.co.uk/1/hi/england/south_wales/7344205.stm>.

\textsuperscript{46} UK Transplant (UKT, <www.uktransplant.org.uk>) was the body responsible for deceased donor organ allocation in the UK at the time of the ‘Ashworth Affair’.

\textsuperscript{47} Human Tissue Authority statement on directed donation of organs after death. Issue dated 14 April 2008.

\textsuperscript{48} TM Wilkinson, ‘What’s not Wrong with Conditional Organ Donation?’ (2003) 29 JME 163–164.
reason to withhold, in the absence of evidence of reward or coercion. The HTA, however, explained that it was bound by the central principle of its existing rules regarding deceased donation. It stated:

In line with this central principle, a person cannot choose to whom their organ can be given when they die; nor can their family. However, the HTA recognizes that there may be exceptional circumstances where this rule might be reconsidered, but the importance of maintaining the central principle means that such exceptional situations would need to be considered with the greatest care before any part of the consent rules were to be changed.49

The statement went on to say that soundings would be taken from suitable bodies as to whether the rules should be changed to allow donation in such exceptional circumstances. But until that had been done, ‘there should be no change in the current system of allocating an organ according to need’.50

In the case under discussion, the request to direct donation of one of the deceased’s kidneys to her mother was not upheld51 and the organs were distributed through UKT, according to the central principle. Although clinical factors may have precluded the possibility of complying with the alleged wish of the donor in any event, the HTA’s statement makes it clear that, even if clinically practicable, her direction would have been disregarded. This authoritative statement makes several assumptions about the legal status of deceased donations under the 2004 Act:

(1) all deceased donations must be unconditional,
(2) any restrictions attaching to donations may be lawfully set aside and the donations treated as unconditional.52

49 Human Tissue authority statement (n 47).
50 Ibid.
51 The Ashworth case contrasts well with a case referred to by Sir Roy Calne in his autobiography The Ultimate Gift (Headline Book Publishing, 1998) of a daughter (Patti) who was permitted to provide a heart to her father (Chester Szuber) after her death in Michigan, USA, in 1994. Patti was killed in a car accident. She had a donor card and there was general agreement that she would have wanted to have donated to her father. The donation was allowed by virtue of discretionary powers expressly vested in OPTN—see Code of Federal Regulations (CFR) 42 121.4 and 121.8, 2005.
52 For a defence of this assumption, see A Maclean, ‘Organ Donation, Racism and the Race Relations Act’ (1999) 149 NLJ 1250–1252. Alasdair Maclean argues that whether it is only the conditions or the ‘gift’ as a whole that is rendered void depends on whether the conditions are precedent or subsequent to the ‘gift’. He maintains that, in the context of deceased donor organ donation, these are conditions subsequent and that it would be lawful to accept the ‘gift’ and ignore the illegitimate pre-conditions in all cases. We consider Maclean’s argument in more detail below.
(3) all deceased donations in the UK must be allocated through UK Transplant, now NHSBT ODT, the national allocation body, in accordance with the central principle of the HTA.

In March 2010, as promised, a policy document on ‘Requested Allocation of a Deceased Donor Organ’ was released. Its most important function is to reiterate and reinforce the two ‘overarching’ principles of unconditionality and equitable treatment for all based on clinical need. Subject to these, however, the document sets out the circumstances in which a request for specific allocation may be considered. These include the death of an intended living donor and other exceptional cases in which an organ from a deceased donor might benefit a close family member or friend. Implementation of the policy is delegated to NHSBT which is given guidelines as to when requests may be granted or refused (usually on the grounds of greater clinical priority elsewhere). The need for compliance with the law, uniform application across the whole of the UK, and full understanding by families of the unconditional nature of organ donation is specifically emphasised. An advisory panel, with members available for consultation at all times, is also established. Although the new policy does introduce some latitude of decision for NHSBT, in cases such as that of Laura Ashworth, the HTA’s statement regarding law and policy and its central principle of unconditionality remain intact.

The position, therefore, appears both clear and resolved. But, is the law really as settled as the HTA contends? In fact, a careful survey of the fundamentals of organ donation law casts doubt on all its assumptions. It will be claimed below that the 2004 Act does not forbid conditional or directed deceased donations, but appears to allow for them in its statutory codes of practice. We will argue that the transplanting of an organ contrary to the terms of a lawful condition is an offence punishable under section 5 of the 2004 Act. We will show that the HTA has no power to vary the words of the Act—its authority is limited to guidance. We will submit that there is no law that requires organs to be distributed only through NHSBT ODT. In fact, with or without attached conditions or directions, they may be transplanted at units throughout the country without any breach of the 2004 Act, provided that they are otherwise lawful. The HTA has no power to prevent such operations. NHSBT ODT’s principle of unconditional donation is certainly lawful, but amounts only to an operational policy. It is entitled to reject conditional donations, but not to vary or

53 Requested allocation of a deceased donor organ <www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_114800>. The document was developed and agreed by all UK Health Administrations, together with the HTA and NHSBT.
discard them without incurring possible criminal liability under the 2004 Act.

III. THE GIFT OF LIFE: PROPERTY OR A MATTER OF CONSENT?

The traditional legal rule has been that the human body cannot be a property. At common law, it is well established that there can be no property in a corpse. This means that a body or body parts cannot generally be stolen. This principle has come under increasing scrutiny in recent years as a result of growing scientific, medical, and possible commercial and criminal considerations. In *R v Kelly*, the Court of Criminal Appeal held that body parts (in that instance, anatomical specimens) could acquire the attributes of property for the purposes of section 4 of the Theft Act 1968 if skilled work had been performed on them. According to Rose LJ, ‘the common law does not stand still. It may be that if, on some future occasion, the question arises, the courts will hold that human body parts are capable of being property for the purposes of section 4, even without the acquisition of different attributes, if they have a use or significance beyond their mere existence. This may be so if, for example, they are intended for use in an organ transplant operation’. This statement carries the suggestion that the unlawful misappropriation of a donor organ might in future be perceived as theft. Indeed, it may be that only the absence of any legal challenge to the ‘unconditional donation’ principle has prevented that conclusion from being drawn already by the courts.

In *R v Kelly*, the preparation of body parts as anatomical specimens was held to be a sufficient act of skill to give them status as property. It is difficult to see why the same status would not be applied to organs

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54 Dr Handyside’s case (1749) 3 East PC 652; Williams v Williams (1852) 20 Ch D 657.
55 See R Hardcastle, *Law and the Human Body* (Hart Publishing, Oxford, 2007).
56 P Matthews, ‘The Man of Property’ (1995 Autumn) 3 Med Law Rev 251–274. See also R Nwabueze, ‘Donated Organs, Property Rights and the Remedial Quagmire’ (2008 Summer) 16 Med Law Rev 201–224, and K Mason and G Laurie, ‘Consent or Property? Dealing with the Body and Its Parts in the Shadow of Bristol and Alder Hey’ (2001) 64 MLR 710–729.
57 See Moore v University of California 793 PD 479 (Cal 1990); and generally B Dickens, ‘Living Tissue and Organ Donors and Property Law: More on Moore’ (1992) Spring J Contemp Health L Pol’y 73–95.
58 *R v Kelly* [1998] 3 All ER 741, 750. See also Report of Nuffield Council on Bioethics, *Human Tissue: Ethical and Legal Issues* (1995) 9.10–10.6. www.nuffieldbioethics.org/go/ourwork/humantissue/publication_298.html
59 *Kelly* (n 58).
60 Ibid.
61 Ibid.
donated for clinical transplantation. Extensive skills have been applied to them to make them suitable for transplantation. These include not only surgical removal and preparation, perfusion with preserving fluid and sterile cold storage, but also the establishment of recipient compatibility by means of tissue typing and cross-matching procedures. None of these ‘high tech’ activities appears inferior in skill to the fairly routine methods considered sufficient by the court in *R v Kelly* to establish property in body parts. In the (not impossible) event of an unconditionally donated organ being snatched from NHSBT ODT for the purpose of organ trafficking, it seems likely that the perpetrator could be convicted of theft in the same way as the defendants in *R v Kelly*. To take the case further, therefore, if an organ allocation body removed a donated organ from the possession of a retrieval team knowing it to be subject to some restriction (e.g. transplantation into a local resident), the stage could be set for prosecution, not only under the 2004 Act, but also under the Theft Act.

The Court of Appeal’s recent decision in *Yearworth v North Bristol NHS Trust*,62 a case which concerned men whose stored sperm samples had been made unusable by avoidable thawing, shows a broader common law acceptance of property rights in general, accompanied by remarks that new (bio)technology demands a more reasoned response from the common law. In *Yearworth*, the Court of Appeal based its decision on the concept that, for the purposes of compensation for negligence, the claimants’ rights over the sperm were essentially those of ownership. While that case concerned living persons and ‘damage to’ rather than ‘loss of’ materials, the court’s statements seem to imply that if the required application of human skill has occurred, then, whatever the position as regards theft, materials intended for transplant might also be capable of being considered as property. If that were really so, one might argue that such materials could, in theory, escape penalties from the offence relating to commercial dealings in the 2004 Act. This would be because although section 32 of the 2004 Act expressly prohibits transplantation for profit, section 32(9) also expressly excludes ‘material which is the subject of property because of an application of human skill’. But this argument and interpretation, however, improperly conflates property with tradability.63 One can quite properly and coherently own something which one may nevertheless not trade.64 Without substantive evidence, it does not logically follow, from the possibility of commerciality, that commodification is in fact legitimate, nor that it can be properly

62 [2009] EWCA Civ 37, [2009] All ER (D) 33 (Feb).
63 Cronin and Price (n 7).
64 J Penner, *The Idea of Property* (OUP, Oxford 1997).
applied to all circumstances within the context of organ donation and transplantation.  However, the above decisions and judicial statements, and this analysis, do highlight a growing uncertainty and ambiguity as to the legal status of human materials, which can probably only be resolved by statute.

IV. CONDITIONAL AND DIRECTED DONATIONS PRIOR TO THE 2004 ACT: NO INHERENT ILLEGALITY

The concept of a body part as property has never been directly considered in the sphere of organ donation. In this context, it appears, as far as the law is concerned, that ‘donation’ of an organ is not a true gift but merely a consent to the process of organ retrieval and transplantation. Although it is not possible to compel acceptance of a donation or any attached condition, no rule of common law prohibits the transplantation of organs into designated recipients, especially if this is done with the consent of those having the duty to dispose of the body—normally the deceased’s personal representatives. Conversely, the transplantation of a body part without consent, or contrary to any condition or direction, has appeared unlikely to lead to any liability at common law, at any rate in the earlier years of transplantation before more recent decisions and judicial statements had lent credence to the idea that the application of human skill to a body part might be able to confer some attribute of property upon it.

The main function of the Human Tissue Act 1961 (hereafter the 1961 Act) was to confirm the lawful nature of organ donation with the donor’s consent or without evidence of objection from the donor and/or their relatives. It has been asserted that it did not envisage conditional donation. However, section 1(1) stated that following the donor’s death ‘any part or, as the case may be, the specified part’ might be authorised to be removed ‘for use in accordance with the request’ (authors’ italics). This does not preclude conditions or directions. In addition, section 1(8) stated: ‘Nothing in this section shall be construed as rendering unlawful any dealing with, or with any part of, the body of a deceased person which is lawful apart from this Act’. Thus, if conditional and directed donations were not unlawful at common law, they remained not unlawful after the 1961 Act.

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65 Cronin and Price (n 7).
66 Williams v Williams (n 54).
67 Dobson v N. Tyneside Health Authority [1996] 4 All ER 474.
68 Kelly (n 58).
69 An Investigation into Conditional Donation (n 6), Ch 4.45.
70 It has been argued that civil liability might have ensued for non-compliance with the 1961 Act. But no case was ever brought under it, and the authors
Whether or not the 1961 Act allowed for the possibility of conditions and directions, it imposed no specific sanctions for non-compliance and so contained nothing to inhibit the general acceptance of ‘unconditional’ donation policies. Indeed, there were a number of clinical and ethical considerations which favoured these. First, it was unlikely that a deceased donor would have been aware of any person who could be designated as a recipient. Second, the requirements of close tissue typing, negative cross-matching and, especially, speed of allocation made it expedient to allow priority to the organ-matching service, whether at local or at national level. Conditions and directions were rare and merely added to an already complicated and time-consuming process. Third, the concept of organ donation as a gift to society was in keeping with the principles of the National Health Service. It had (and still has) considerable public support.

In 1998, a case of attempted conditional deceased organ donation produced widespread public controversy and led to government intervention. The condition, which required restriction of allocation to white recipients only, circulated briefly through the organ allocation service before being discarded as contrary to its policy of unconditional donation. Mr Frank Dobson, the then Secretary of State for Health, made an immediate statement to the effect that conditional donation was ‘completely unacceptable’, followed by a further statement (together with the President of the British Transplantation Society) affirming that ‘organs must not be accepted if conditions about the recipient are attached’. The report of a specially appointed panel, ‘An Investigation into Conditional Organ Donation’, appeared in 2000. Although most of its conclusions used the word ‘unacceptable’, rather than ‘illegal’, it did appear to concede that the absence of sanctions would have excluded criminal liability. See Mason and McCall Smith, Law and Medical Ethics, JK Mason and GT Laurie (eds) (7th edn OUP, Oxford 2006) s 14.38, p 493.
take advice (unreferenced) on ‘key points’ of the law. These seemed to be:

(i) The Human Tissue Act 1961 ‘did not envisage conditional agreement. Either the donor...agrees to a part of his, or her, body being used for donation after death, or they do not’.

(ii) There is no duty on a potential donor ‘to agree to the use of their organs after death, however offensive or irrational the reasons for refusing to do so’

(iii) ‘Racist’ conditions, if wrongly accepted by the NHS, must be ignored, and the organ used for the most suitable recipient, irrespective of race, since otherwise there may be a breach of the Race Relations Act 1976. But

(iv) ‘If an organ has been inadvertently accepted with a racist condition attached, the fact that the condition cannot be put into effect does not invalidate the agreement to donate for the purposes of the 1961 Act. The organ can still be used’.79

The panel’s final conclusions mirrored those of the Secretary of State. All conditional donations were unacceptable. Chapter 6.9 of the report recommended that the policy of unconditional donation should now be formalised, making it clear that ‘it applies to all conditions and not just those of a racist kind, and that the opportunity should be taken to set out what the law requires in this area’.80

The report thus reinforced the idea that all deceased conditional donations must be illegal. But, while some of the panel’s legal surmises were correct (e.g. that there is no duty to donate organs to the NHS under UK law), others were not. In particular, as seen, nothing in the 1961 Act precluded conditional donations and the freedom to ignore conditions was not an effect of that Act, but merely a reflection of its lack of sanctions. In addition, the report failed to take account of the fact that the UK organ-sharing scheme was then (and remains still, rightly or wrongly) a matter of cooperation rather than compulsion. Individual units were free to pursue their own deceased organ donation policies, provided that the general law was respected—under the 1961 Act, as seen, this was not difficult. In the years before the 2004 Act, it was possible for conditional or directed kidney donations to be performed locally if local opportunity and policy allowed it, as the national organ-sharing policies allowed local units to retain one kidney for use at their discretion.81

79 Ibid.
80 Ibid, ch 6.9. Emphasis added.
81 UKT Allocation Protocol 2003. See SV Fuggle and others, ‘Human Leucocyte Antigen and the Allocation of Kidneys from Cadaver Donors in the United Kingdom’ (2007) 77 Transplantation 618–620.
What specific conditions or directions might be illegal under the general law has never been tested in the courts. One clear case would be a donation for reward. Parties to such a procedure would face prosecution\(^\text{82}\); and others can be envisaged. The condition attempted in the 1998 case (restriction to a racial group) appears \textit{prima facie} illegal, as amounting to discrimination under the race relations legislation.\(^\text{83}\) However, the position may be more complex than suspected. While the organ allocation body was free to reject the donation as infringing its policy, the Race Relations Act 1976 did not, in 1998, extend to discrimination by public bodies (introduced by the Race Relations (Amendment) Act 2000). In addition, section 35 of the 1976 Act states: ‘nothing…shall render unlawful any act…affording persons of a particular racial group access to facilities or services to meet the special needs of persons of that group in regard to their education, training or welfare…’ (authors’ italics). NHSBT ODT’s allocation policy currently gives preference to recipients with blood groups and tissue typing commonly found among ethnic minorities. The reason is that due to a lower donation rate among such communities, combined with a higher incidence of renal failure, access to deceased donor transplantation is otherwise difficult.\(^\text{84}\) This form of ‘covert’ discrimination is outlawed by section 1(b) of the 1976 Act,\(^\text{85}\) although it may be protected either by section 35 or by the claim (section 1(b)(ii)) that it is justifiable irrespective of racial origin. However, if this is lawful, it is unclear why a donation in favour of any other ethnic group, overt or covert, should not also be protected.

To summarise the position prior to the 2004 Act, the dominant role of the organ allocation body, backed by the ‘gentlemen’s agreement’ of individual units to abide by its policies, the unenforceability of conditions under the common law, the purely permissive nature of the 1961 Act, unsupported by sanctions for non-compliance, the dislike of the government and allocation authority for conditional donations,

\(^{82}\) Human Tissue Act 2004 s 32 (formerly Human Organ Transplants Act 1989 s 1).

\(^{83}\) Race Relations Act 1976 s 1.

\(^{84}\) UKT Allocation Protocol 2003. See \textit{Fuggle and others} (n 81). Ethnic minorities (who have a high incidence of blood group B) comprised 22% of the UK transplant waiting list, but only 2% of deceased organ donors. In 2002, by allowing certain organs from blood group O donors to be allocated to blood group B recipients, an increased donation rate for this group was achieved, to the disadvantage of the blood group O recipients (mainly white) who would otherwise have received them.

\(^{85}\) And more specifically by s 1A, inserted (19 July 2003) by the Race Relations Act 1976 (Amendment) Regulations 2003 (SI 2003/1626). These expressly apply to health care.
and the absence of any rigorous legal analysis through challenge in the courts combined to produce the following assumptions:

(a) The acceptance policy represented the law. Therefore,
(b) conditional and directed donations were inherently unlawful; and
(c) such donations could be allocated unconditionally, as if the attempted restrictions did not exist.

These assumptions were those of the report of the Investigation into Conditional Donation of 2000. But, they were incorrect. They accurately reflected the policy of the allocation body, but received no support from either common law or statute.

V. THE HUMAN TISSUE ACT 2004: THE PRIMACY AND VALIDITY OF ‘APPROPRIATE CONSENT’

In 2000, the former allocation body, the United Kingdom Transplant Support Service Agency (UKTSSA), a Special Health Authority set up in 1991, was replaced by UKT whose remit included an obligation actively to promote organ donation.86 No alteration in policy or law resulted: but a change in the legal status of all donations was about to take place. The 2004 Act, which repeals and replaces earlier legislation,87 significantly altered the law. Organ donation now became unlawful, except under defined circumstances. The main relevant new rules are as follows:

(1) The 2004 Act permits authorised activities for certain scheduled purposes to be carried out. The 2004 Act covers seven scheduled purposes requiring general consent, one of which is transplantation.88
(2) Authorised activities are only lawful if done with ‘appropriate consent’.89
(3) Unauthorised dealings are now criminal offences, carrying penalties.90
(4) A regulatory body, the HTA, has been set up to oversee and control the working of the Act.91
(5) Codes of practice establish guidelines for practice, especially as regards the meaning and extent of ‘appropriate consent’. It is thus

86 <http://www.uktransplant.org.uk/ukt/newsroom/fact_sheets/pdfs/about_us_0209.pdf>.
87 Human Tissue Act 2004 (n 1).
88 Ibid, s 1.
89 Ibid, s 3.
90 Ibid, s 5.
91 Ibid, Part 2 s 13–15.
92 Ibid, s 26.
essential to know the precise meaning of ‘appropriate consent’ since otherwise criminal liability may be incurred.93

How do these changes affect conditional or directed deceased donations? Two important principles are unchanged. First, NHSBT ODT’s policy is unaffected—it remains free to reject conditional or directed donations. Secondly, there is still no compulsion for donated organs to be allocated solely according to NHSBT ODT’s policies—alternative arrangements remain possible, provided that they do not contravene the terms of the 2004 Act. The most important change stems from the application of the new principle of ‘appropriate consent’ to the declared policy of discarding attempted conditions and directions in favour of unconditional allocations.94

‘Appropriate consent’ requirements for adults fall under section 3 of the 2004 Act. No distinction is made between consent for the purpose of tissue retention and that for organ donation. Although, in several defined situations, proxy consent is legal under the 2004 Act,95 here we will examine only the position of a deceased adult donor who had been competent to give or withhold consent in person, because the same principles of interpretation apply in each situation. Section 3(6) states:

Where the person concerned” (the donor) “has died…‘appropriate consent’ means

(a) if a decision of his to consent to the activity, or a decision of his not to consent to it, was in force immediately before he died, his consent.

In 2006, the HTA issued a Code of Practice regarding consent,96 after it had been approved by Parliament. Although the Codes are important and intended to be influential, section 28 of the 2004 Act states that failure to comply with their provisions does not, of itself, render a person liable to legal proceedings. In view of the HTA’s express rejection of the legality of conditional donations, one might expect the Code to have reinforced this position. But, in fact, para 105 states;

93 Ibid, s 3.
94 Human Tissue Authority statement (n 47).
95 For children (s 2), for persons without legal capacity (s 6), by nominated representatives (s 4) and, in the absence of consent, by persons in a ‘qualifying relationship’ (ss 3.8 and 27 (4)).
96 Human Tissue Authority Code of Practice on Consent (Code 1, July 2006)—specifically required by s 26(3). This code should now be considered in conjunction with the Revised Codes of Practice, Donation of Solid Organs for Transplantation issued by the HTA in September 2009.
Consent can be:

- General, i.e. if someone consents to the use of tissue for research, it need not be limited to a particular object
- Specific, i.e. a person limits their consent – a sample can only be used for research into a particular condition
- Both general and specific, i.e. a general consent subject to specific exceptions.

It is true that the examples given by the 2006 Code seem to refer to cases of proposed tissue retention for research: but both the 2004 Act and the Code make it clear that, in section 3, ‘general provision is made for adults to consent to the use of their material for a range of purposes, including research and organ transplantation’.97 If consent is not required to be unrestricted, or ‘generic’98 in the context of donations for research, the same must apply to consent for deceased organ donation for transplantation since neither the 2004 Act nor the Codes make any distinction as to the nature of the consent involved in these two situations. In 2009, a Revised Code of Practice not only restated the difference between generic and specific consent but also emphasised that it should be valid, i.e. given voluntarily by an ‘appropriately informed’ and competent person.99

It may be argued that ‘appropriate consent’ in section 3 of the 2004 Act must be read in the light of Parliament’s true intention (which, in keeping with the central principle of the HTA and UKT (now NHSBT ODT), must have been to ensure that restrictions on deceased donations should be illegal) and interpreted accordingly. But, this does not survive analysis. The basic principle of statutory interpretation is that the intention of Parliament ‘has to be ascertained from the words which it has used and those words are to be construed according to their plain and ordinary meaning’.100 An interpretation of consent which overrides any attached restrictions is hardly in such a category. The plain fact is that the 2004 Act is completely silent on conditional and directed deceased donations101 and cannot be construed so as to appear to provide for them. Furthermore, this argument offends the principle

97 McHale and Fox (n 71) 1100, 1131.
98 On the objections to generic consent as a negation of donor autonomy or possible religious and cultural objections, see McHale and Fox (n 71) 1127. See also JV McHale, ‘Regulating Genetic Databases: Some Legal and Ethical Issues’ (2004) 11 Med Law Rev 70.
99 Revised Code of Practice 2, Donation of Solid Organs for Transplantation issued by the HTA in September 2009 paras 30–34.
100 Pickstone v Freeman [1989] AC 61, (Lord Oliver).
101 See Cronin and Price (n 7). See also McHale and Fox (n 71) at 1100, 1128–29.
whereby Parliament is presumed not to abrogate common law rights other than by express words or necessary implication. At common law, a party’s consent, given without the knowledge that his or her attached conditions will be ignored, amounts to uninformed consent, as it is ‘expressed in form only, not in reality’ and so may be held to have been vitiates. The HTA’s Revised Code of Practice 1, Consent (2009) actively stresses the need for consent to be informed if it is to be valid.

VI. THE CONSEQUENCES OF PROCEEDING WITHOUT VALID CONSENT

The conclusion from this interpretation of consent is clear but disconcerting. If a donor’s consent has been limited to specific situations, it follows that any allocation of organs contrary to such limitations vitiates that consent and amounts to dealing with the organs without consent. Although it appears that NHSBT ODT (or any other organ user) remains free to reject such donations as contrary to its allocation policy, NHSBT ODT is not free to accept the donation while ignoring the restriction. The conclusion of the Investigation into Conditional Donation in 2000 can no longer be followed with impunity, despite the HTA’s recent statement on the directed donation case. To do so would be an offence under section 5 of the Act. It has been argued already that conditional and directed donations have never been illegal per se, as they are not prohibited by any law. But, even if a restriction were held to be illegal (e.g. under the Race Relations Acts), it does not follow that it could then be disregarded for the purposes of establishing consent to unconditional donation. On the contrary, like any other qualification, it would tend to vitiate the donor’s consent, raising the prospect of criminal liability as a result.

In ignoring the donor’s intentions and allocating organs unconditionally, a number of persons and bodies could become liable to prosecution under section 5 of the 2004 Act. The teams directly involved in the donation and transplantation activity are obvious candidates. However, although strict liability under statute is always a possibility, the terms of section 5(1), which requires a ‘guilty mind’, offers them a defence. This states that a person will not be liable if he ‘reasonably believes . . . that he does the activity with appropriate consent’. Although all persons are presumed to be cognisant of the law, the fact that the

102 R v Home Secretary ex parte Simms [2000] AC 115, 1131 (Lord Hoffman).
103 Chatterton v Gerson [1981] 1 All ER 257.
104 Chatterton v Gerson (n 104) (Bristow J).
105 Human Tissue Authority statement (n 47).
teams rely, in good faith, on the legality of both the donations offered by NHSBT ODT and the policy statement of the HTA (even though wrong) appears to protect them. Next in line is NHSBT ODT (as the allocating authority) which, while not directly involved under section 5(1), is covered by section 5(2) which states:

‘A person commits an offence if

(a) he falsely represents to a person whom he knows or believes is going to, or may, do an activity…

(i) that there is appropriate consent to the doing of the activity, or

(ii) that the activity is not one to which the subsection applies, and

(b) he knows that the representation is false or does not believe it to be true’.

However, as NHSBT ODT and its agents also have a reasonable (though wrong) belief in the correctness of the HTA pronouncements, they too are probably (though less clearly) immune from liability.

The final candidate is the HTA itself.\textsuperscript{106} It is a statutory corporation\textsuperscript{107} whose remit\textsuperscript{108} and functions\textsuperscript{109} include both the maintenance of the general principles that it considers should be followed and the provision of oversight and guidance for those involved in organ donation and transplantation. Undoubtedly capable of criminality\textsuperscript{110} even if a guilty mind is required,\textsuperscript{111} its statement of 14 April 2008 identifies it as potentially liable for the purposes of section 5(2).\textsuperscript{112} Could it, however, rely on its erroneous, but honest, misinterpretation of the law in that statement as a defence? In our opinion it cannot. While the clinical teams and NHSBT ODT are protected by their reliance on its advice, which they reasonably regard as authoritative, the HTA itself has no such bulwark and cannot plead misunderstanding of the law any more than any other defendant. Although we have no wish to see it prosecuted, we contend that the errors in its policy statement, if put into effect in a case of directed deceased donation,

\textsuperscript{106} Although the HTA’s agents could in theory be personally liable under s 5(2) of the 2004 Act, the delegated nature of their work and the central identification of the HTA with the policy statement of 14 April 2008 (n 4) make it unnecessary to consider their position here.

\textsuperscript{107} Human Tissue Act 2004, s 13.

\textsuperscript{108} Ibid, s 14.

\textsuperscript{109} Ibid, s 15.

\textsuperscript{110} The option of a fine as penalty under s 5(7) of the 2004 Act reinforces this position.

\textsuperscript{111} See Kite (Peter Bayliss) [1996] 2 Cr App R (S) 295, CA 249.

\textsuperscript{112} See Tesco Supermarkets v Nattras [1972] AC 153.
would inevitably place the final liability upon the regulatory authority itself.\textsuperscript{113}

It may be argued that in the Laura Ashworth case, the HTA did not, in fact, commit any offence because the donor’s intention should be construed as merely to give priority to her mother, with a more general consent to unconditional donation if that should prove clinically impossible. However, such an intention would need to have been presented immediately before death\textsuperscript{114} and could not lawfully be constructed later in the light of what appeared clinically desirable. In addition, the HTA’s official statement confirms its intention to continue ignoring such conditions for the time being, leaving it at risk of prosecution in future cases.\textsuperscript{115} A somewhat analogous argument regarding construing a donor’s intention was advanced by Alasdair Maclean in 1999 with respect to the ‘racial condition’ donation of 1998.\textsuperscript{116} Maclean suggests that a distinction between conditions precedent to a donation, which formed part of it and could not be separated from it, and conditions subsequent which, being attached as an afterthought to a ‘gift’ which was already unconditional, should be properly disregarded. Although ingenious, this argument appears to be a contrived attempt to arrive at an ethically acceptable solution that does not sit easily with the rules of statutory interpretation.

The policy document ‘Requested Allocation of a Deceased Donor Organ’\textsuperscript{117} requires (para 20) that, in discussing requests, it is vital that family members should understand that, although requests can be considered in certain circumstances, donation must never be conditional on the requested allocation going ahead. This raises an interesting point on consent. If the family, after discussion, voluntarily agrees to make the donation unconditional, a subsequent decision by NHSBT not to allow the request (e.g. because of an alternative high priority recipient) would appear to be lawful. But if, as seems more likely in view of NHSBT’s misunderstanding of the law, the family acquiesces in the unconditionality only because it mistakenly believes that it has no other choice, its consent would be vitiated by this misinformation and as a result any failure to honour the request would become illegal.

\textsuperscript{113} In general, there is a tendency for the courts to be lenient. For two opposing cases, see Sec of State for Trade and Industry v Hart [1982] WLR 481 and Grant v Bond [1982] WLR 638. But since neither of these cases involved a statutory body, it is not clear what view the courts might take of breaches of the law mistakenly committed by members of such bodies.

\textsuperscript{114} Human Tissue Act 2004, s 3(6).

\textsuperscript{115} Human Tissue Authority statement (n 47).

\textsuperscript{116} Maclean (n 52).

\textsuperscript{117} Requested allocation of a deceased donor organ (n 53).
Supporters of the HTA’s ‘unconditional’ policy might further argue that, even if not strictly prohibited in law, directed and conditional donations cannot take place in practice, since, even if it is an offence under the 2004 Act to overrule them, NHSBT ODT is nevertheless under no obligation to give effect to them and, in deference to its central principle, apparently will not do so. As a result, these attempted donations simply will not happen. This argument would have a considerable weight if non-compliance with NHSBT ODT’s allocation policies were an offence or subject to sanctions, as in the USA, where under the National Organ Transplant Act 1984 (NOTA), failure to comply with the statutory policies of the Organ Procurement and Transplant Network (OPTN) may lead to exclusion from the Medicare and Medicaid programmes, as well as to other penalties. But in the UK, because, as already shown, deceased donations without reference to NHSBT ODT appear to incur no legal sanctions (although they might attract the disapproval of the HTA), it would be possible for any transplant centre to step in and give effect to an otherwise lawful directed or conditional donation on its own initiative, rather than lose a rare, and clinically vital, opportunity for the recipient. This would not lessen the overall importance of NHSBT ODT, whose co-operation for the majority of donations (which are, by their nature, unconditional) is essential. It would only be likely to apply in circumstances in which the ‘unconditional’ policy of NHSBT ODT and the HTA conflicted with an (equally lawful) ‘discretionary’ approach on the part of the local unit.

It is interesting to note that in the USA, although compliance with OPTN’s policies is mandatory, its powers of enforcement are combined with considerable freedom to devise ‘equitable’ allocation policies. The Code of Federal Regulations (CFR) expressly provides that ‘Nothing in this section shall prohibit the allocation of an organ to a recipient named by those authorised to make the donation’. In addition, the US Uniform Anatomical Organ Gift Acts from 1968 to 2006, which provide the authority for deceased organ donation, also permit donations to be made to specific individuals. The condition is that if the specified donation turns out to be impossible, the organ is to be

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118 See National Organ Transplant Act, US Code, Title 42 ss 273–274 and Code of Federal Regulations (CFR) 42 (Public Health) Subchapter K 121.1–11, 2005.
119 CFR 42 121.10(c), 2005. See SV McDiarmid and others, ‘The Oversight of Solid Organ Transplantation in the United States’ (2008) 8 Am J Transplant 739–744.
120 CFR 42 121.4 and 121.8, 2005.
121 All the US states have adopted in their state laws one version or another of the Uniform Anatomical Gift Acts.
allocated according to OPTN rules.\textsuperscript{122} Thus, the American law leaves an opening for personal autonomy under reasonable circumstances,\textsuperscript{123} while still retaining an underlying ethic of impartial justice. The American laws appear to provide for a degree of discretion very similar to that which the HTA, in its statement on the Ashworth case, seemed to consider desirable for itself—if only it were not bound by the law. Somewhat ironically, our analysis shows that it is not so bound and already possesses that discretion. There is also evidence to suggest that public opinion in the UK would not be hostile to its exercise in suitable situations.\textsuperscript{124}

The above interpretation of the 2004 Act could have further consequences. As it does not prohibit conditional or directed donations, and these are not illegal \textit{per se}, it could be possible for donors to bypass NHSBT ODT’s national allocation policy by requiring their organs to be used only in their own locality or NHS Region. Although unlikely to become a reality under the current system of close co-operation, it might well attract significant widespread public support\textsuperscript{125} if, for instance, severe organ donor shortage and increased regional ‘devolutionary’ tendencies were to coincide. Such conditions or directions would have to be accepted by both NHSBT and local transplant units or else rejected completely, on pain of criminal liability—with the legally permissible, but socially and clinically deplorable, the result that the organs would be unused unless the donor immediately before death had agreed that local recipients should have priority only. Another result could be a strengthening of the concept of property in organs, as already discussed, because the unconditional national allocation of an organ by the authority in defiance of a donor’s directions for local or regional allocation might raise the possibility of its being prosecuted for theft.

\section*{VII. CONCLUSIONS}

The reinforcement by statute of the legal status of conditional and directed donations has come about unnoticed, as there is no evidence

\begin{itemize}
\item[\textsuperscript{122}]Uniform Anatomical Gift Act 2006 ss 11(b) and 11(g)(3).
\item[\textsuperscript{123}]We would like to acknowledge the help of Mr Ronald Richenburg, Principal Assistant Librarian, Bodleian Law Library, Oxford University in accessing this information.
\item[\textsuperscript{124}]J Neuberger and D Mayer (n 74). In a representative quota sample of 2015 adults (aged 15 years and over), there was a wide spread of opinion. While 60\% of respondents, in general, favoured unconditional donation, some conditions had significant support—e.g. priority to children (59\%), exclusion of alcoholics from liver donation (39\%), and priority to family (36\%).
\item[\textsuperscript{125}]Neuberger and Mayer (n 124).
\end{itemize}
that Parliament contemplated such a result.\textsuperscript{126} How can that be? There are a number of possible reasons.

(1) It has not been appreciated how little legal regulation existed before the 2004 Act. In particular, the inchoate nature of the common law meant that little or nothing had been decided on the legality of donation and the nature of consent. It was not realised, for example, that since conditional or directed consent was not inherently illegal it must be lawful unless forbidden.

(2) The purely permissive nature of the Human Tissue Act 1961 and its lack of sanctions for non-compliance allowed UKT (now NHSBT ODT) to operate a policy of unconditional donation which was widely, but wrongly, assumed to represent the law. But, in the absence of any law compelling donation to (now) NHSBT ODT, individual units remained free to follow any lawful donation policy.

(3) The stance taken by the government following the 1998 ‘racial’ donation inhibited consideration of donations which, although restricted in some way, might be ethically acceptable.

(4) The rarity and clinical inconvenience of such donations meant that very little thought was given to them;

(5) \textit{The Report of the Investigation into Conditional Donation 2000}\textsuperscript{127} had the opportunity to analyse the true legal position, but discarded it in favour of asserting the NHS policy as if it were established law;

(6) The drafting decision to require the same definition of ‘appropriate consent’ in both organ donation and tissue retention had the important, though unintended, consequence of creating legislative support for the concept that consent for deceased organ donation need not be unrestricted.

(7) The rarity of any legal challenge to the policies of the NHS and its statutory bodies (let alone any successful one) has discouraged analysis of their legality, which tend to be followed unquestioningly even when those bodies themselves are not satisfied with their application. This legally unnecessary assumption of subordination appears both in the attitude of ULTRA to its authority under the HOT Act 1989 and in the comments of the HTA after the Ashworth case.

In spite of the influence of all these factors, it remains surprising that the HTA should be so mistaken about the nature and limitations of its authority that it runs the risk of becoming criminally liable under its own enabling statute criminally liable under its own enabling statute.

\textsuperscript{126} See D Price, ‘The Human Tissue Act 2004’ (2005) 68 MLR 798–821, 812.\textsuperscript{127} An Investigation into Conditional Organ Donation (n 6).
Perhaps the best explanation is that the huge proliferation of statutes, regulations, codes of practice, guidelines, ministerial pronouncements, etc. in this area of NHS practice (as in others) has, in many minds, blurred the distinction between law and policy. In addition, the ‘monopolistic’ authority of the NHS may act as a disincentive to constructive criticism—an undesirable situation, if true. But penalties, while creating new perils, have also brought about one unforeseen change. Whatever the ethical arguments for or against them, conditions and directions attached to deceased donations, though unenforceable, cannot simply be ignored. As long as the present statutory framework of consent and authorisation persists as the basis upon which deceased donor organs become available for clinical transplantation, they must be taken account of in establishing the validity of ‘appropriate consent’. Moreover, because they are not inherently illegal, there is no (lawful) reason why they should not be put into effect, at discretion, in appropriate circumstances, if otherwise lawful. This conclusion appears to chime with some public opinion and does not seem to be unwelcome to the HTA. But, in a wider perspective, the situation is disturbing, for it suggests that the intrusion of government into the world of organ donation and transplantation has been accompanied by a significant degree of incomprehension and that those who administer the transplant laws do not fully understand their consequences.