

Opt-Outs and Upgrades

Ethics and Law in the United Kingdom

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Abstract: We report on two areas in which UK law and ethics seem out of step with each other. 2013 saw the passing of the Human Transplantation (Wales) Bill, which will introduce an opt-out system of organ donation in Wales from 2015. In the first section, we discuss the convoluted evolution of the Bill and some potential problems that we consider may prevent it from achieving its intended goal of increasing the number of organs transplanted. The prospect of being able to enhance human cognition through cognitive-enhancing drugs (“smart drugs”) also presents a nexus of questions associated with future ambitions, hopes, and concerns as a society. How these drugs might affect the future of work and employment is beginning to generate wide public engagement in the UK and forms the focus of the second section.

Keywords: organ donation; organ transplantation; opt out; presumed consent; cognitive-enhancing drugs; smart drugs; Ritalin; modafinil; human enhancement

Law and ethics, as in many intimate relationships, can easily get out of step with each other. We report on two areas in medicine in which this seems to have happened recently in Britain. In the case of organ donation, remarkable progress has been made over the past five years in improving the number of organs available for transplant in the UK, yet Wales has insisted on legislating for change in its law, which could lead to unethical practice and could jeopardize what has been achieved so far. In the use of cognitive-enhancing drugs, however, legislation is lagging well behind current trends in social behavior, and ethical analysis of “mind enhancement” is progressing well in advance of UK law.

The Human Transplantation (Wales) Bill 2013

The United Kingdom¹ looks set soon to be divided over organ transplantation. Currently the whole of the UK operates an opt-in system of organ donation for transplantation from dead donors. The Human Tissue Act (HTA) 2004 makes “lawful if done with appropriate consent”² both the removal and the use “from the body of a deceased person, for use for a purpose specified in Schedule 1 [including transplantation³], of any relevant material of which the body consists or which it contains.”⁴ The “appropriate consent” is usually considered as given by joining the organ donor register⁵ maintained by NHS (National Health Service) Blood and Transplant (NHSBT) organization. However, as two recent books on the ethics of organ acquisition have clearly demonstrated, though there is in fact no direct ethical requirement in the UK to obtain express consent of either the deceased or their relatives before taking organs after death,⁶ “there is clearly a deep feeling that *someone* should give positive consent for organ retrieval.”⁷

On July 2, 2013, the National Assembly of Wales voted to adopt what they describe as “a soft opt-out system for consent to deceased organ and tissue donation in Wales from 2015.”⁸ When implemented, this will be a landmark change in

transplantation policy (and possibly practice) in Wales, and the recent political background to the vote is worth recounting.

Organ Donation Law in the UK

In 2006–7 there were just more than 14 million people on the NHS Organ Donor Register, and though 3,000 transplants were carried out, 1,000 people died while still on the waiting list.⁹ At that time, the government commissioned the UK Organ Donation Task Force, which reported in 2008¹⁰ and set a target of increasing the number of organs for donation after death in the UK by 50 percent by 2013, an ambitious target that was nevertheless achieved.^{11,12} A change from the current opt-in system, however, had not been among the 14 recommendations made in the report, which focused instead on issues concerning donor identification and referral, donor coordination, and organ retrieval.

In 2010, however, the task force produced another report specifically examining the introduction of an opt-out system in the UK. It concluded that the issue was “finely balanced,” with several factors supporting a change—for example, opinion polls revealed 60 percent public support for the idea—but also considerable evidence “highlighting the potential downside of such a move.”¹³ The task force commented “that moving to an opt out system . . . may deliver real benefits but carries a significant risk of making the current situation worse,” for example, by damaging “the vital relationship of trust between clinicians caring for people at the end of life, their patients and their families.”¹⁴ They concluded they were “not confident that the introduction of opt-out legislation would increase organ donation, and there is evidence that donor numbers may go down.”¹⁵

The UK’s highly influential Nuffield Council on Bioethics also produced a consultation paper in 2010 on ethical issues concerning the use of human tissue, including consent for postmortem transplantation, the responses to which informed their definitive 2011 report, *Human Bodies*.¹⁶ The working party for that report commissioned a review of donation legislation in other countries,¹⁷ including opt-out arrangements, and concluded that “in practice such systems differed less than might be imagined from the ‘opt-in’ system in the UK.”¹⁸ In particular they noted that in Spain, which has the highest donation rates in Europe, “there is no requirement to express opposition to organ donation in any particular form, and hence it is standard practice to seek ‘consent’ from the family.”¹⁹ The Nuffield report made no recommendation to change to an opt-out system in the UK, a view still currently taken by the Department of Health, perhaps not surprisingly, because the most recent figures for the year ending March 31, 2013,²⁰ show a total of 4,111 organ transplants, of which 3,112 were from dead donors—an increase of 6.8 percent on the previous year, with a corresponding reduction of the waiting list of more than 3 percent, to 7,532. There were more than 19.5 million people on the organ donor register by the end of March 2013²¹—a rise of 22 percent in five years.

The Evolution of the Human Transplantation (Wales) Bill 2013

In 2007, NHS Wales published *Designed to Tackle Renal Disease in Wales: A National Service Framework*.²² The section on transplantation aimed to find “ways to try and improve the donation rate from both living and cadaveric donors, and

to provide guidance on how each donated kidney can be used to its maximum potential.²³ Its first proposed key intervention was “to increase public awareness of the need for organ donation, to encourage people to enrol on the organ donor register and to make their wishes known to those close to them”; no mention was made of introducing an opt-out system.²⁴ In July 2008, the Welsh Health, Well-Being and Local Government Committee produced a report entitled *Inquiry into Presumed Consent for Organ Donation*. It concluded,

The most urgent and productive steps for improving donation rates rest with the early implementation in Wales of the UK Organ Donation Task Force (ODTF) recommendations. We do not rule out introducing presumed consent in Wales at some point in the future. However, we do not believe that it is currently the most urgent priority and believe that it could be a distraction from other, more productive actions.²⁵

Despite the lack of evidence supporting introducing an opt-out system in Wales, in October 2008 the Welsh Assembly launched a public discussion document²⁶ on an opt-out proposal. By September 2009, the Assembly’s report on the responses received to the consultation concluded, “The majority of responses supported a change to the organ donation consent system in Wales to a soft opt-out system” (p. 6).²⁷ This eventually led to a white paper in November 2011 proposing the opt-out legislation, which has now been adopted in the Bill.

While all the activity was underway to legislate for the introduction of presumed consent, the implementation of the 2008 ODTF-recommended strategies resulted in a 91 percent increase in organs transplanted in Wales from 2008–9 to 2011–12²⁸—way in excess of the goal of 50 percent set by the ODTF for the whole of the UK. Furthermore, though the figures for 2012–13 show a rise of 6 percent in the number of organs transplanted in the UK overall,²⁹ the number in Wales fell by 12 percent (to 211) from the previous year³⁰—the year during which donation in Wales had been discussed more than in the rest of the UK, with all the public consultation concerning the Welsh Bill.

Ambivalence over Opt-Out Policies

The Bill’s soft opt-out policy is explained by the Welsh Assembly as follows: “A person’s consent to donation will be deemed to have been given unless they objected during their lifetime—a process called opting out—but where those closest to the deceased will still have an important role to play in the process.”³¹ However, exactly what that role is is very far from clear. The text of the Bill does allow for relatives to object to organ acquisition when “(a) a relative or friend of long standing of the deceased objects on the basis of views held by the deceased, and (b) a reasonable person would conclude that the relative or friend knows that the most recent view of the deceased before death on consent for transplantation activities was that the deceased was opposed to consent being given.”³² However, a soft opt-out system is generally understood as one in which the relatives have the right of veto over donation if the deceased’s wishes were unknown or disputed.³³ The Human Transplantation (Wales) Bill, as passed, has the potential to be interpreted in practice as a hard opt-out system—a system in which organs may be taken against the relatives’ wishes; this system currently operates in Austria³⁴ but had to

be repealed when introduced in Brazil³⁵ and was rapidly revised in Chile³⁶ because it had a deleterious effect on donation rates. In Singapore, which extended a hard opt-out system to include liver, heart, and corneas in 2005, the rate of 5.9 deceased organ donors per million population in that year fell by 22 percent, to just 4.6 per million by 2009.³⁷ Much of this fall was probably related to the public reaction to the distressing case of Sim Tee Hua in 2007.³⁸ When an opinion piece advocating a hard opt-out system in the UK was published very recently in the *BMJ*,³⁹ not a single one of the responses submitted online agreed with the author's view.⁴⁰

The Influence of the Welsh Bill on the Whole UK

Though the Welsh Bill is not due to be implemented in Wales until 2015, it has already prompted moves toward similar changes in other parts of the UK. Two Early Day Motions to introduce a nationwide opt-out system were tabled in the Westminster Parliament in the autumn of 2011,^{41,42} one of which specifically referred to the Welsh initiative. The British Medical Association, which has for some time been in favor of the introduction of an opt-out system,⁴³ immediately hailed the "opt-out organ donation law as one of the most important pieces of legislation in Welsh history."⁴⁴ A week after the passing of the Welsh Bill, a BBC article claimed that "the NHS is considering preventing families from overriding the consent of people who have signed the organ donor register."⁴⁵ In it, the director of the NHSBT was reported as asking, "Is it right to allow our organs to be buried or cremated with us when they could save or improve the lives of up to nine people?"

In Scotland, the *Glasgow Evening Times*, which for several years has been running the influential Opt for Life campaign to introduce an opt-out system, immediately urged the Scottish Parliament to follow Wales' lead, and Drew Smith, a member of the Scottish Parliament, pledged to introduce a member's Bill to this effect if the Parliament does not act.⁴⁶ Finally, in Northern Ireland, Jo-Anne Dobson, the mother of a successful transplant patient and a member of the Stormont Assembly, is planning to introduce a private members Bill to introduce an opt-out system in the province.⁴⁷

We consider it likely that when the Welsh Bill is enacted in 2015, both pragmatic border issues and political momentum will mean that the whole of the UK will eventually follow suit. The Welsh Bill's arrangements regarding Welsh residents who die in other parts of the UK and other permutations regarding residency⁴⁸ are so complex that the implementation of them will be both costly and difficult, especially when relatives cannot be contacted. Though there is a large transplantation center in Cardiff, where most patients in South Wales are treated, those living in North Wales often have their transplants carried out in England. Though the difficulties of differing legislation in the two regions are not insuperable, clearly there will be enormous pressure to unify the position throughout the UK.

Given that the introduction of the opt-out system and the opt-in register will have to be run in parallel for many years and also that the Welsh Assembly considers that the whole population will need to be fully informed about the possibility and practicalities of opting out, it will be a slow and costly procedure. Its promised benefits are by no means certain in the light of international experience as a whole.⁴⁹ Trust is a delicate moral fabric and not easily restored when damaged; if the Welsh Bill is interpreted and practiced as a hard opt-out system, public

confidence in the NHS transplant system as a whole could be undermined. As transplant surgeon Dorry Sergev recently commented, “With opt-out the perception becomes, ‘We will take your organs unless you take the time to fill out a form.’ That’s a dangerous perception to have.”⁵⁰ We consider it advisable to see what happens first to organ donation rates in Wales from 2015 to 2020 before extending an opt-out system to other parts of the UK.

“Smart Drugs”

Public discussion concerning the use of cognitive-enhancing “smart drugs” (nootropics) is intensifying in the UK^{51,52,53} as more people experiment with them. A poll by Cambridge University’s *Varsity* newspaper revealed that 1 in 10 students use cognition-enhancing drugs such as modafinil, whereas 1 in 3 said that they would take concentration-enhancing medication if offered the opportunity.⁵⁴

Data have revealed that the number of stimulants prescribed in England has been rising steadily from 220,000 in 1998 to 418,300 in 2004.⁵⁵ In November 2011, the BBC’s *Newsnight* program ran an anonymous online questionnaire that sought to gather data on the use of cognitive-enhancing drugs. Of the 761 people who replied, 38 percent said they had taken cognitive-enhancing drugs, 40 percent said they had bought the drugs online, and 92 percent said that they would use them again.⁵⁶ On the global scale, an online issue of *Nature* indicated that, of 1,400 respondents from 60 countries, 1 in 5 said that they had used drugs for nonmedical reasons as a cognitive enhancer.⁵⁷

This is not an issue of which the UK government is unaware. Its horizon-scanning and future-planning center, Foresight, has predicted that “pharmacological enhancement of cognition in both the young and old healthy populations seems set to become increasingly popular, extending from dietary supplements and caffeine to drugs specifically targeted at improving cognition.”⁵⁸

The Impact of Smart Drugs on the Workforce and Work Culture

The prospect of being able to enhance human cognition presents a nexus of questions associated with future ambitions, hopes, and concerns as a society. One way of framing this debate, which is beginning to generate wide public engagement in the UK, is by looking at the impact of smart drugs on the workforce and working conditions. In an economic climate causing us to assess how to generate more with less, the attraction of working longer hours but with increased levels of concentration and stamina is obvious. Because people need to continue working later in their lives—leading to a heightened risk of age-related memory loss—could cognitive-enhancing drugs be part of the answer? Accidents in the workplace can often be attributed to employees losing concentration, so could safety in the workplace also be improved through the use of cognitive-enhancing drugs, irrespective of the age of the employee? In America, modafinil is already used among shift workers in order to reduce accidents.⁵⁹

The Work Foundation has recognized the potential cognitive-enhancing drugs may well have in the workforce, suggesting that perhaps the next great leap in terms of work culture is using these drugs to improve concentration, to allow us to work without sleep, to minimize impulsivity, and to improve planning and development of ideas.⁶⁰ In fact, the Work Foundation chose this subject as the

focus of its annual debate in 2013,⁶¹ demonstrating the importance they attribute to such developments.

Similarly, *Human Enhancement and the Future of Work*, a recent report by some of the UK's most respected science institutions—the Academy of Medical Sciences, the British Academy, the Royal Academy of Engineering, and the Royal Society—also recognizes the very real possibility of cognitively enhanced, super-alert workers in the future. In reviewing new technologies, the report found that “work will evolve over the next decade, with enhancement technologies potentially making a significant contribution.”⁶² The report goes on to comment that in the specific case of cognitive-enhancing drugs, they could be used to “treat individuals with neuropsychiatric disorders [and] could also improve mental faculties such as memory and concentration in healthy individuals, enabling them to work more efficiently or for longer.”⁶³

Experts report that experiencing a decline in cognitive abilities is very often the reason why many people are not able to return to work after having experienced episodes of depression and schizophrenia. Cognitive-enhancing drugs can help to treat these kinds of disabilities while simultaneously improving mental capacity and well-being. Current estimates indicate that by 2026 the cost of mental health disorders in England will rise to £88.4 billion, nearly half of which will be as a result of lost earnings (£40.9 billion).⁶⁴ There are therefore clear economic benefits to investing in the development of treatments for neuropsychiatric disorders in the working population.

But on the other hand, at what cost are we attaining this increased concentration? Are we increasing work productivity at the expense of quality of life? Could creativity, which generally requires relaxation and the loosening of mental concentration, actually be lost rather than improved in light of the fact that concentration is heightened through the use of cognition enhancing drugs? Research to date yields a mixture of results on this point,⁶⁵ but there is evidence to suggest that there are limits to the effectiveness of such drugs and that it depends on the baseline creativity of an individual. Cognitive-enhancing drugs may help to raise creativity in lower-performing individuals while inhibiting it in naturally high-performing individuals.⁶⁶ Nevertheless, there are genuine concerns over the kind of society that could be created if the use of cognitive-enhancing drugs became more widespread. Would we use these drugs to make work more rewarding and efficient, which in turn would afford us more opportunities to enjoy life and take up more hobbies and recreational pursuits? Or would we take the opportunity to work more and for longer, creating an accelerated, 24/7 work culture? Will employees face being coerced into using cognitive-enhancing drugs in order to keep their jobs, or to even be offered a job in the first place? If steps are taken to enhance older workers, will this negatively affect younger people trying to find work? And on a wider perspective, could the use of cognitive-enhancing drugs drive forward the competitiveness of user countries within the global village, forcing other countries to consider national enhancement programs in order to maintain their competitive edge?

The Regulation of Smart Drugs

Discussion of national programs leads to policy and regulatory issues. Currently little is known either about user habits or of the longer-term side effects of taking smart drugs. The advent of the Internet has provided a ubiquitous means through

which individuals, in the comfort and privacy of their own homes, can purchase smart drugs, helping to shape a “closet phenomenon.”⁶⁷ In order to responsibly address the issue of these drugs, the topic needs to be brought out into the open and proactively engaged with, rather than being merely ignored or dismissed as the activity of a select minority.

An isolated discussion, devoid of public involvement, can be dangerous for industry, risking the possibility of a public reaction like that which emerged following the genetically modified (GM) crops issue. Early upstream engagement is essential in order to garner not only public opinion but also public confidence in future developments. This in turn will help to shape and direct economic decisionmaking.

In terms of specific legislation of cognitive-enhancing drugs, there are no UK frameworks currently in place, although we do know that the drugs remain strictly off license in both the UK and the United States.⁶⁸ This presents the question of how these drugs will be obtained and distributed. The UK’s Foresight project acknowledged that the current regulatory processes may not be adequate to effectively manage the potential ready availability of cognition enhancers.⁶⁹ In 2009, the UK Home Office asked the Advisory Council on the Misuse of Drugs to see how this “rapidly evolving field” should be regulated amid fears from medical experts that the range of drugs available could fuel an overcompetitive society when used by the healthy.⁷⁰ There is a real need for the government to build on such work and to help to increase consultation on these issues and develop a long-term strategy for public engagement on this issue.

Crucial to any regulatory model for the use of drugs for enhancement by healthy people is the issue of safety. Cognitive-enhancing drugs have been primarily developed for those people suffering from neuropsychiatric disorders and brain injuries. Consequently, there is a lack of long-term safety studies of these drugs and their effects on healthy people. How should the risks of using these drugs be mitigated? In order to assess these risks, regulators would need long-term data and safety studies in order to base their decision as to whether or not to extend their licenses. Leadership is needed on this issue, as pharmaceutical companies do not appear to be responding with appropriate action to instigate such studies. Cognitive enhancers such as Ritalin are classified in the UK as a controlled drug, whereas modafinil is not, thus making it legal to buy the latter online, though still illegal to supply it without a prescription.⁷¹ Using the Internet to procure drugs in this way always presents problems, not least in terms of authenticating the source from which you are purchasing as well as simply trying to enforce regulation on a medium that transcends geographical borders. The UK Medicines and Healthcare Products Regulatory Agency (MHRA), part of the UK government’s regulation and safeguarding arm of its healthcare system, has made the matter of the illegal sale and supply of medicines over the Internet a priority.⁷²

Do Smart Drugs Promote Human Well-Being?

Talk of any form of human enhancement often quickly leads to questions concerning the creation of a social divide between the haves and have-nots. The economist Fred Hirsch has argued that the pursuit of what he terms “positional goods” should be discouraged. These goods accrue value because only some people have them, whereas others do not. If society as a whole pursued positional goods,

it would be a waste of time and resources. As Hirsch neatly puts it, “if everyone stands on tiptoe, no one sees any better.”⁷³ Improved cognitive functioning has been argued to bring with it nonpositional benefits. Bostrom and Roache report that economic models of the financial loss caused by small intelligence decrements due to lead in drinking water demonstrate significant economic effects with a decline of only a few points in IQ scores.⁷⁴ Thus, significant benefits could be expected if a small amount of intelligence was in fact gained by only part of society “enhancing” itself. Improving cognition could therefore bring not only benefits to the individual but also cultural and economic benefits to society as a whole.⁷⁵

The idea of the human condition being one of continuing to seek improvement of itself may be true to a certain extent. Nevertheless, could it also be argued that what makes us human is our variety without conformity. Every effort should be made to alleviate suffering and disease, but at the same time we must keep in balance the real value of forms of enhancement. However, this line of argument assumes that there is a discoverable boundary between health and illness—something that is not easy to establish. Some would even argue that such a boundary does not exist. Thus the therapy/enhancement paradigm does not seem to provide an adequate response to the most pertinent questions that seem to be of primary concern: that of inequity, abuse, and control.

These kinds of concerns were noted in the High-Level Expert Group report from the European Commission,⁷⁶ with reference to the prospect of the “pursuit of happiness.” The EU report argued that there should not be “engineering of the mind and of the body” but rather “engineering for the mind and for the body,” which would somehow maximize our humanity without taking us beyond it. Although helpful, critics have attacked this distinction by pointing out that it presupposes that a bright line can be clearly drawn between peripheral technologies—external tools and aids that may augment function and the underlying hardware. Bostrom and Roache suggest that we move away from a therapy, disease-focused framework and adopt instead an approach (particularly in terms of regulation) that focuses more on human well-being.⁷⁷ A benefit of pursuing this path could be to help facilitate the much-needed regulation of the development of cognitive-enhancing drugs for use by healthy adults.

Notes

1. The United Kingdom of Great Britain and Northern Ireland, along with the Republic of Ireland, together make up the British Isles. Great Britain is made up of Scotland, England, and Wales.
2. HTA 2004, part 1; available at www.legislation.gov.uk/ukpga/2004/30/section/1 (last accessed 8 Nov 2013), at 1c.
3. HTA 2004, schedule 1, part 1. Purposes requiring consent; available at <http://www.legislation.gov.uk/ukpga/2004/30/schedule/1> (last accessed 20 Mar 2014), at 7.
4. See note 2, HTA 2004.
5. NHSBT. How to become a donor; available at http://www.organdonation.nhs.uk/how_to_become_a_donor/ (last accessed 8 Nov 2013).
6. Wilkinson TM. *Ethics and the Acquisition of Organs*. Oxford, UK: Oxford University Press; 2011, at 101.
7. Richards JR. *The Ethics of Transplants—Why Careless Thought Costs Lives*. Oxford University Press; 2012, at 156.
8. Welsh Government. *Human Transplantation (Wales) Bill*; available at <http://wales.gov.uk/topics/health/nhswales/majorhealth/organ/?lang=en> (last accessed 8 Nov 2013).
9. Organ Donation Task Force. *The Potential Impact of an Opt-Out System for Organ Donation in the UK*; 2010; available at <http://www.odt.nhs.uk/pdf/the-potential-impact-of-an-opt-out-system-for-organ-donation-in-the-UK.pdf> (last accessed 23 May 2014), at 6, 2.1.

10. Organ Donation Task Force. *Organs for Transplant*; 2008; available at <http://www.bts.org.uk/Documents/Publications/Organs%20for%20transplants%20-%20The%20Organ%20Donor%20Task%20Force%201st%20report.pdf> (last accessed 8 Nov 2013).
11. Keogh B 2013 Letter to the Organ Donation Task Force Delivery Board 19th April 2013 http://www.ics.ac.uk/latest_news/organ_donation_taskforce_b_keogh
12. BBC News 2013 Organ donation soars after past five years <http://www.bbc.co.uk/news/health-22086086> Accessed November 8, 2013.
13. See note 9, Organ Donation Task Force 2010, at 1.1, 1.6, 1.8.
14. See note 9, Organ Donation Task Force 2010, at 1.14, 1.9.
15. See note 9, Organ Donation Task Force 2010, at 11.5.
16. Nuffield Council. *Human Bodies: Donation for Medicine and Research*; 2011; available at http://www.nuffieldbioethics.org/sites/default/files/Donation_full_report.pdf (last accessed 8 Nov 2013).
17. The countries included in the review were Belgium, India, Iran, Israel, Spain, and the United States (at both the federal and the state level). The review focused on specific issues for each country, rather than attempting a detailed overview of every aspect of the legislation governing the donation of bodily material.
18. See note 16, Nuffield Council 2011, at 2.26.
19. See note 16, Nuffield Council 2011, at 2.26.
20. NHSBT. *Organ Donation and Transplantation—Activity Figures for the UK as at 12 April 2013*; available at http://www.organdonation.nhs.uk/statistics/downloads/annual_stats.pdf (last accessed 8 Nov 2013).
21. NHS Organ Donor Register; 2013; available at http://www.organdonation.nhs.uk/statistics/downloads/united_kingdom_april13.pdf (last accessed 21 Mar 2014).
22. NHS Wales. *Designed to Tackle Renal Disease in Wales: A National Service Framework*; 2007; available at <http://www.wales.nhs.uk/sites3/documents/434/Designed%20to%20tackle%20renal%20disease%20in%20wales%20-%20eng.pdf> (last accessed 8 Nov 2013).
23. See note 22, NHS Wales 2007, at 142.
24. See note 22, NHS Wales 2007, at 144.
25. Welsh Government Assembly. *Inquiry into Presumed Consent for Organ Donation*; 2008; available at <http://www.assemblywales.org/cr-ld7192-e.pdf> (last accessed 8 Nov 2013).
26. Welsh Government Assembly. *Discussion Document: Introduction of an Opt Out (Presumed Consent) System in the Context of Organ Transplantation*; 2008; available at <http://wales.gov.uk/dhss/publications/health/guidance/discussion/discussionconsente.pdf;jsessionid=FB078736449B5C511552F996531C8CF4?lang=en> (last accessed 8 Nov 2013).
27. Welsh Assembly Government. *Options for Changes to the Organ Donation System in Wales*; 2009; available at <http://www.wales.nhs.uk/sites3/Documents/773/Organ%20Donation%20consultation%201doc%20-%20English.pdf> (last accessed 23 May 2014).
28. NHS Blood and Transplant. *Organ Donation and Transplantation Activity Data: WALES*; 2014; available at http://www.organdonation.nhs.uk/statistics/downloads/wales_mar14.pdf (last accessed 24 May 2014).
29. NHS Blood and Transplant. *Organ Donation and Transplantation Activity Data: UNITED KINGDOM*; 2014; available at http://www.organdonation.nhs.uk/statistics/downloads/united_kingdom_mar14.pdf (last accessed 24 May 2014).
30. See note 28, NHS Wales 2014.
31. Welsh Government. Organ donation; available at <http://wales.gov.uk/topics/health/nhswales/majorhealth/organ/?lang=en> (last accessed 8 Nov 2013).
32. *Human Transplantation (Wales) Bill*; available at <http://www.senedd.assemblywales.org/documents/s18966/Bill%20as%20passed%20unchecked.pdf> (last accessed 8 Nov 2013).
33. *Consent for Organ Donation*; available at http://www.dohc.ie/consultations/closed/Donation_of_Organs/consentoptions.pdf?direct=1 (last accessed 8 Nov 2013).
34. Rithalia A, McDaid C, Sukarran S, Myers L, Sowden A. Impact of presumed consent for organ donation on donation rates: A systematic review. *BMJ* 2009;338:a3162.
35. Csillag C. Brazil abolishes “presumed consent” in organ donation. *Lancet* 1998;352(9137):1367. “Presumed consent” is a problematic term and should not in our view be equated with “opting out,” as it is possible to have an opt-out system that does not presume consent. It is interesting that in Wales the term “deemed consent” has been used in the actual Bill—though this term also does not necessarily equate with an opt-out system.

36. Dominguez J, Rojas JL. Presumed consent legislation failed to improve organ donation in Chile. *Transplantation Proceedings* 2013;45:1316–17.
37. ETCO-EDC. IRODaT organ donation and transplantation activity data, various years; available at <http://www.europantransplantcoordinators.org/clinical-resources/irodat/> (last accessed 21 Aug 2012).
38. Xin L. Forced organ removal in Singapore raises concerns. *The Epoch Times*; 2007; available at <http://www.theepochtimes.com/news/7-4-3/53670.html> (last accessed 8 Nov 2013).
39. Shaw D. We should not let families stop organ donation from their dead relatives. *BMJ* 2012;345:e5275.
40. See note 39, Shaw 2012, responses section of the online publication; available at <http://www.bmj.com/content/345/bmj.e5275?tab=responses> (last accessed 8 Nov 2013).
41. UK Parliament. Early day motion 2407; available at <http://www.parliament.uk/edm/2010-12/2407> (last accessed 8 Nov 2013).
42. See note 41, UK Parliament.
43. Mayor S. Opt-out scheme is still best way to increase organ donation, says BMA. *BMJ* 2012;344:e1098.
44. BMA 2013. Wales passes organ donation opt-out law; available at <http://bma.org.uk/news-views-analysis/news/2013/july/wales-passes-organ-donation-opt-out-law> (last accessed 8 Nov 2013).
45. Walsh F. “Stop families” from overriding donor consent; 2013; available at <http://www.bbc.co.uk/news/health-23260057> (last accessed 8 Nov 2013).
46. Wilson C. Scotland urged to follow Wales in organ donation opt-out. *Glasgow Evening Times* 2013 July 3; available at <http://www.eveningtimes.co.uk/opt-for-life/scotland-urged-to-follow-wales-in-organ-donation-opt-out-129327n.21505753> (last accessed 8 Nov 2013).
47. Louise-Connolly M. Organ donation: Public to be consulted on proposed law change; 2013; available at <http://www.bbc.co.uk/news/uk-northern-ireland-22757477> (last accessed 8 Nov 2013).
48. Welsh Government. *Human Transplantation (Wales) Bill: Explanatory Memorandum Incorporating the Regulatory Impact Assessment and Explanatory Notes*; 2012; available at <http://www.assemblywales.org/bus-home/bus-business-fourth-assembly-laid-docs/pri-ld9121-em-e.pdf?langoption=3&ttl=PRILD9121-EM%20-%20Human%20Transplantation%20%28Wales%29%20Bill%20-%20Explanatory%20Memorandum> (last accessed 8 Nov 2013).
49. Boyarsky B, Hall EC, Deshpande NA, Lorie Rois R, Montgomery RA, Steinwachs DM. Potential limitations of presumed consent legislation. *Transplantation* 2011;93:136–40.
50. Johns Hopkins Medicine Press Release; 2011 Nov 29; available at http://www.hopkinsmedicine.org/news/media/releases/presumed_consent_not_answer_to_solving_organ_shortage_in_us_researchers_say (last accessed 8 Nov 2013).
51. Taylor P. Think positive: The rise of “smart drugs.” *PMLiVE* 2013 June 18; available at http://www.pmlive.com/pharma_news/think_positive_the_rise_of_smart_drugs_483056 (last accessed 14 July 2013).
52. Chilton M. Hay Festival 2013: Leading neuroscientist warns against “smart drugs.” *Telegraph* 2013 May 25; available at <http://www.telegraph.co.uk/culture/hay-festival/10080593/Hay-Festival-2013-Leading-neuroscientist-warns-against-smart-drugs.html> (last accessed 14 July 2013).
53. Sahakian B, LaBuzeta JM. *Bad Moves: How Decision Making Goes Wrong, and the Ethics of Smart Drugs*. Oxford, UK: Oxford University Press; 2013.
54. Lennard N. One in ten takes drugs to study. *Varsity* 2009; available at <http://www.varsity.co.uk/news/1307> (last accessed 1 Feb 2012).
55. Parliamentary Office for Science and Technology. Better brains. *POSTNote* 2007 June;285; available at <http://www.parliament.uk/briefing-papers/POST-PN-285.pdf> (last accessed 11 July 2013).
56. Do cognitive-enhancing drugs work? *BBC News Online* 2011; available at <http://www.bbc.co.uk/news/health-15600900> (last accessed 11 July 2013).
57. Maher B. Poll results: Look who’s doping. *Nature* 2008;452:674–5.
58. Sahakian B, Morein-Zamir S, Robbins T, Turner D, Sahakian B. Mental capital and wellbeing: Making the most of ourselves in the 21st century. Pharmacological cognitive enhancement. Government Office for Science; available at http://www.bis.gov.uk/assets/foresight/docs/mental-capital/sr-e9_mcw.pdf (last accessed 8 Nov 2013).
59. Wellcome Collection. *Superhuman: Exploring Human Enhancement from 600 BCE to 2050*. London: Wellcome Collection; 2012, at 34.

60. Bevan S. Cognitive enhancement—The next leap forward in productivity? *The Work Foundation Blog*; 2013 May 31; available at <http://www.theworkfoundation.com/blog/1208/Cognitive-enhancement-the-next-leap-forward-in-productivity> (last accessed 11 July 2013).
61. See note 60, Bevan 2013.
62. Academy of Medical Sciences, British Academy, Royal Academy of Engineering, Royal Society. *Human Enhancement and the Future of Work: Report from a Joint Workshop Hosted by the Academy of Medical Sciences, the British Academy, the Royal Academy of Engineering and the Royal Society*. London: The Academy of Medical Sciences; 2012 Nov, at 5; available at http://royalsociety.org/uploadedFiles/Royal_Society_Content/policy/projects/human-enhancement/2012-11-06-Human-enhancement.pdf (last accessed 11 July 2013).
63. See note 62, Academy of Medical Sciences et al. 2012, at 13.
64. King's Fund. *Paying the Price: The Cost of Mental Health Care in England to 2026*; 2008; available at http://www.kingsfund.org.uk/publications/paying_the_price.html (last accessed 1 Feb 2013).
65. See note 62, Academy of Medical Sciences et al. 2012, at 16.
66. See note 62, Academy of Medical Sciences et al. 2012, at 16.
67. Bannerman L. Bring “smart drugs” out of the closet, experts urge government. *The Times Online*; 2010 Feb 27; available at <http://www.thetimes.co.uk/tto/science/medicine/article5102.ece> (last accessed 11 July 2013).
68. Hyland MJ. The drugs do work: My life on brain enhancers. *The Guardian* 2013 May 3; available at <http://www.guardian.co.uk/lifeandstyle/2013/may/03/brain-enhancing-drugs-mj-hyland> (last accessed 11 July 2013).
69. Horizon Scan, Office of Science & Technology. Cognitive enhancers summary. *Drugs Future 2025?*; available at <http://www.bis.gov.uk/foresight/MediaList/foresight/media%20library/BISPartners/Foresight/docs/brain-science/~media/BISPartners/Foresight/docs/brain-science/cognition-enhancers-summary.ashx> (last accessed 11 July 2013).
70. Travis A. Government watchdog considers ban on IQ booster drugs. *The Guardian* 2009 July 28; available at <http://www.guardian.co.uk/politics/2009/jul/28/watchdog-intelligence-performance-psychoactive-drugs> (last accessed 11 July 2013).
71. See note 56, Do cognitive-enhancing drugs work?, 2011.
72. Medicines and Healthcare Products Regulatory Agency (MHRA). Press release: Warning over Internet sales of counterfeit weight loss medication; 2010 Jan 25; available at <http://www.mhra.gov.uk/NewsCentre/Pressreleases/CON068520> (last accessed 11 July 2013).
73. Hirsch F. *Social Limits to Growth*. London: Routledge & Kegan Paul; 1977, at 5.
74. Bostrom N, Roache R. *Smart Policy: Cognitive Enhancement and the Public Interest*; 2009; available at <http://www.nickbostrom.com/papers/smart-policy.pdf> (last accessed 11 July 2013).
75. See note 74, Bostrom, Roache 2009.
76. EU High Level Expert Group. *Foresighting the New Technology Wave: Converging Technologies—Shaping the Future of European Societies*; 2004; http://ec.europa.eu/research/social-sciences/pdf/ntw-report-alfred-nordmann_en.pdf (last accessed 11 July 2013), at 21.
77. See note 74, Bostrom, Roache 2009.