Highlights from this issue

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Governmental coercion in the name of health

Frequently ethical debates turn not on the defensibility of philosophical presuppositions or the logical rigor of argumentation, but on empirical matters of fact. In an engaging and provocative article examining the empirical and ethical dimensions of compulsory cycling helmet laws, Carwyn Hooper and John Spicer (***see page 338***, *Editor's choice*) argue that the evidence as to whether helmets non-marginally reduce the risk of head injuries while cycling is inconclusive, and hence that more empirical investigation is warranted before compulsory helmet legislation be put in place. The authors concede that were it the case that compulsory cycle helmet laws (like their motorcycle counterparts) significantly reduced the incidence of serious head injuries, this would amount to a strong *prima facie* case for the legislation. The centerpiece of their empirical critique takes aim at studies demonstrating an overall decrease in the incidence of head injuries in legal jurisdictions that have instituted mandatory helmet laws for cyclists. Most assume that this epidemiological pattern is explained by the protection afforded by helmets, but as the authors rightfully point out it might instead be due to the fact that fewer people choose to cycle when they are forced to wear a helmet. Because we cannot use existing data to adjudicate between these alternative explanations, they argue, additional empirical work should be carried out before any compulsory legislation is passed. *Contra* the authors, I do not believe it is necessary that we exhaustively rule out all plausible rival explanations before acting at the population level in the interest of human wellbeing, especially in the context of what, on the face of things, appears to be fairly commonsensical conclusions from the data.

More forceful, in my view, is their political philosophical assault on such legislation. Their central claim is that although there are thresholds of competent risk-taking beyond which the state may legitimately intervene (such as with respect to highly addictive drugs or motorcycling without a helmet), the risks associated with cycling simply do not rise to this level. The overall probability of sustaining a head injury while cycling is minuscule. Philosophical foundations of the liberal state require that individuals be accorded great personal latitude to engage in health-affecting behaviour without substantial governmental intrusion, such as smoking in private, consuming alcohol, eating fatty and high caloric foods, skiing, marathon running, mountaineering and so forth. It seems unfair and undesirable to require that individuals shoulder greater shares of the cost burden in order to compensate society for their mildly risky lifestyles. As the authors note, basic notions of fairness imply that similar cases of risk be treated in similar ways. While there is no special moral or legal right to cycle with one's hair to the wind, I am sympathetic to the authors' contention that the freedom to determine personally acceptable levels of risk is part of the fabric of liberal society. Unless the risks to cyclists are shown to be substantial, and the causal connection between helmet-wearing and reduced head injuries can be firmly established, it seems difficult to justify such legislation.

Human biological tissue research: commercialisation and consent

Human body parts, including organs and even simple tissues, are widely regarded as *res extra commercium*: objects that exist outside of commerce and thus cannot be sold or traded in the marketplace. Restrictions on the alienation of human tissues are motivated by ethical concerns surrounding the commodification of human life more broadly, including worries about encouraging instrumentalist attitudes towards persons and the exploitation of vulnerable populations. Preventing individuals from transferring their own biological tissue in exchange for a financial reward is thought by many to protect the value of autonomy itself and the social attitudes that allow it to flourish. This view is codified in a variety of major European legal instruments, including the *European Convention on Human Rights and Biomedicine* (1997), which holds that 'the human body and its parts shall not, as such, give rise to financial gain'. Many have inferred from such language that the human body and its components are not to be considered property at all (***see page 347***). This makes it all the more striking that European hospitals have *legally* transferred residual biological materials without knowledge or consent of the patient source to global firms that trade in the international market in human tissues. In a paper exploring the legal dimensions of human tissue commercialisation, Christian Lenk and Katharina Beier (***see page 342***) examine the main legal documents governing human tissue transfer in the European Union. They argue that these instruments have in fact left room for weaker forms of commercialisation. This interpretive latitude would explain why these rules, when read literally, appear to be routinely disregarded in medical practice in various European nations. The authors consider a graded model of human tissue commercialisation, ranging from the strong principle that human tissue is not property and thus cannot be sold under any conditions even with consent of the donor (most closely approximated in the UK); to restricted sale conditions requiring that the donor consent to commercialisation; to government regulated tissue prices with or without donor control (the current situation in Belgium); to full commercialisation on the free market without any donor control. This graded model and its instantiations highlight the significant international variation in approaches to the regulation of tissue commercialisation.

In a related paper, Gefenas *et al* (***see page 351***) examine novel approaches to consent in the context of research on residual human biological materials that were obtained and/or archived for therapeutic or diagnostic purposes. The authors consider three types of consent regimes that avoid the impracticable scenario of seeking subsequent consent (or a waiver thereof) as future research uses arise. The first is precautionary consent, which contains no specifics with regard to potential research uses; the second is presumed consent, involving an opt-out procedure; and the final holds that no consent or institutional ethical review is required, declaring in effect that research on anonymised human tissue does not

amount to research on human subjects. The authors endorse a compromise position amounting to a qualified precautionary consent regime, which entails providing the patient with particularised information about potential research uses at the time of collection. I agree with the authors that departures from post-WWII consent procedures in the context of biological residuals are justified, but I am less convinced that they have offered conclusive objections to the alternative presumed consent/no consent frameworks.

Neuroenhancement

The biomedical enhancement of cognitive function is no longer the stuff of philosophical thought experiments. There is currently a large-scale and widely publicised 'off-label' use of drugs that were developed and approved to treat neurocognitive disorders, but that are now commonly used to enhance the cognitive performance of healthy individuals. Most think that were we able to determine that there were no adverse side effects associated with a given cognition-enhancing drug, any remaining ethical concerns would be unlikely to justify a prohibition given the benefits and liberty interests at stake. In an interesting and well-argued paper, Heinz *et al* (***see page 372***) challenge the empirical assumption that pharmaceutical neuroenhancements will ultimately offer benefits that exceed their adverse effects. Their central worry relates to the problem of addiction: Due to their unique neurobiological effects, psychotropic enhancements will tend to be far more addictive than uncontroversial cognition-enhancing substances, such as coffee, to which pharmaceutical neuroenhancements are often—and if the authors are right, inappropriately—compared. Because of the neurological architecture underlying learning and memory, the authors suggest that neuroenhancements will unavoidably affect motivational systems that are modulated by dopaminergic pathways implicated in addiction phenomena. They conclude that the addiction potential of neuro-enhancing drugs is not a contingent characteristic of extant pharmaceuticals, but rather an inexorable side effect of any pharmacological attempt to improve cognition.

Furthermore, the authors argue that the empirical validity of this theoretical claim cannot be tested without subjecting healthy research subjects to an unfavourable risk-benefit ratio, given the addiction potential involved. If they are right, then there are major if not insurmountable ethical obstacles to carrying out the empirical investigation that is needed to resolve this dispute. It seems, however, that the inevitable, pervasive and potentially dangerous use of cognition-enhancing drugs calls for clinical trials to assess their addiction potential and other adverse effects. Whether research participants in such trials would be subjected to inappropriate levels of risk, all things considered, will depend on our estimates of the intrinsic addiction propensity of the medication at issue and whether it can be adequately monitored and mitigated during study. These are questions better answered by neuroscientists specialising in addiction research.

Healthcare resource allocation: The problem of new technologies

Increasing moral philosophical attention is being devoted to conflicts between present and future generations in the allocation of important resources. In an excellent analysis of one such conflict in the context of emerging medical technologies, Stephen Holland and Tony Hope (***see page 366***) explore the conflicting interests of present and future patient populations when it comes to expanding the evidence base for resource allocation decisions. Between the binary choice of approving or rejecting a new medical technology lies a third class of allocation decision in which access is made contingent on the gathering of additional empirical data regarding the clinical efficacy and cost-effectiveness of the technology under consideration. This third avenue offers a way of securing the present benefits of a prospective technology while at the same time managing risk and improving future allocation decisions. The authors provide a helpful typology and ethical analysis of such decisions, focusing on the ethical conflict between future populations who stand to benefit from additional evidence gathering on the one hand, and the lost opportunity costs imposed on present populations by evidence-conditional allocation decisions on the other. They conclude that even if the weight of future people should be discounted as compared to presently existing people, we cannot justify affording future people no weight at all in the decision calculus. Astutely, they point out that allocation deciders implicitly give moral consideration to the interests of future people when they require a reasonably high standard of evidence—rather than merely a better chance than not—that an intervention will be cost-effective. Granting access to new technologies conditioned on evidence development reflects the deep moral intuition, unfazed by the philosophical 'non-existence problem', that the interests of future people count.