Human Rights, Bioethics and Human Experimentation

Richard Ashcroft
Professor of Biomedical Ethics
Queen Mary, University of London

Introduction: From Nuremberg to Northwick Park

It is customary to link the modern form of human rights, in declarations, legislation, institutions and social movements to the determination of the international community to say "Never again" to the horrors of the Third Reich. Aside from the Holocaust itself, one of the most powerful examples of the evils of Nazism is the violation of human bodies and minds practised in the concentration and death camps in the name of human experimentation. If one wished to illustrate the nature of human rights violations, a very good way to do so would be to describe the experiments and investigations conducted by the men convicted at the Nuremberg Doctors' Trial of 1946-1947 and their associates. It is customary also to identify the Nuremberg Doctors' Trial, and the Nuremberg Code enunciated in the judgment handed down at that Trial, as one of the seminal texts of modern bioethics.

From this it would be natural to assume that bioethics and human rights approaches to human experimentation are essentially cognate, and should very largely overlap. If one were to look for differences, these might be the difference between bioethical theory and human rights practice, or the difference between the academic work of scholars and the practical work judges, policy-makers and activists. And indeed differences there are, but this contrast between theory and practice, or theorists and practitioners, does neither capture all of the differences between bioethical and human rights approaches to human experimentation, nor explain all of those differences.

In this short paper I want to explore those differences and what they tell us about the limitations of both bioethics and human rights approaches to human experimentation in the context of an example. Human rights activists have intermittently been very interested in human experimentation in the 60 years since Nuremberg, but they have shown a particularly strong interest in the last ten years or so due to their engagement with the ethical, legal and human rights aspects of HIV/AIDS, and with the globalisation of both the pharmaceutical industry and the medical research enterprise. To illustrate: the conduct of clinical trials of HIV prevention, both horizontal transmission between sexual partners or people sharing drug injecting equipment and vertical between mother and child, has been beset by controversies over the use of placebo control when effective treatment is known to exist but is too expensive for widespread use in the trial's host communities and the availability of HIV medication to people who have become infected during the trial or who were receiving it during the trial but cannot afford to receive it once their participation in the trial is over. A large literature has grown up framing this as a complex human rights violation, and to some extent this way of framing the problem has had political successes in the form of the Doha Declaration regarding the TRIPS agreement and compulsory licensing of patented medications, the mobilisation of a large international "access to essential medicines" movement under a human rights banner, and so on. Equally, this taking up of the challenges

of international clinical trials and the global drug supply in human rights form has caused controversy within bioethics, where many commentators have argued that the human rights approach to this issues is unhelpful, or that it involves a simplistic understanding of the needs of users and obligations of industry and medical professionals, or that other approaches within bioethics, political philosophy and law are more effective in practice and more illuminating in theory than the human rights model.

In the time available to me I cannot even scratch the surface of these issues, so instead I will take a simpler, but I hope interesting, example, this time in the developed world. As many of you will know, there was a high profile instance of a clinical trial going disastrously wrong in the UK in early 2006. This has come to be known as the Northwick Park incident. I think it is quite helpful in illustrating the different ways in which bioethics and human rights scholars approach the issues of human experimentation.

To review the facts of the case, I refer you to the independent expert report on the incident prepared for the UK Health Ministers and published in November last year:

> On March 13, 2006, six healthy male volunteers received TeGenero's TGN1412 drug and two received a placebo in a phase one, first-in-man, clinical trial run by Parexel, a contract research organization. The Parexel unit was in rented space on the Northwick Park Hospital site in London. TGN1412 is a monoclonal antibody that was being developed as a new medicine for the treatment of B cell leukaemia and autoimmune diseases. Within hours of receiving TGN1412, all six volunteers were admitted to the intensive care unit at Northwick Park Hospital with a very severe systemic inflammatory reaction that progressed to multi-organ failure.[1]

All eight volunteers were previously healthy. Subsequently, it is reported that all six affected volunteers did make a recovery, but it is not yet clear what the long-term consequences of exposure to the drug will be. All were paid to take part, although it is not clear how much – figures of the order of £2000 are quoted. In the aftermath of the disaster, two official reports were commissioned. The first, which reported in May 2006, was the Medicines and Healthcare Regulatory Authority's review of the clinical trial itself and the MHRA's inspections of the clinical trials facilities. This report had the narrow functions of regulatory review, and checked whether the MHRA's standards for "good clinical practice" had been adhered to, and concluded the following:

> This investigation indicates that the adverse incidents did not involve errors in the manufacture of TGN1412 or in its formulation, dilution or administration to trial participants. The MHRA therefore concludes that an unpredicted biological action of the drug in humans is the most likely cause of the adverse reactions in the trial participants. Monoclonal antibodies are a relatively new type of biological drug although there are a number of them already licensed and in use. However, TGN1412

[1] Expert Scientific Group on Phase One Clinical Trials *Final Report: 20th November 2006* London: The Stationery Office: 13. Available at: http://www.dh.gov.uk/PublicationsAndStatistics/Publications/PublicationsPolicyAndGuidance/PublicationsPolicyAndGuidanceArticle/fs/en?CONTENT_ID=4141039&chk=Qczxoq (Accessed 9-2-07)

> is a new class of monoclonal antibody which has a stimulatory mode of action affecting certain types of cell in the immune system. In this case the resulting activity seen in humans was not predicted from apparently adequate pre-clinical testing. This is a complex scientific issue which raises important scientific and medical questions about the potential risks associated with this type of drug and how to make the transition from preclinical testing to trials in humans.[2]

The reports themselves have been criticised, although they have in the main been welcomed. One criticism is that the MHRA could not independently review the study, since if its conclusion that there was nothing wrong with the manufacture or administration of the drug itself was correct, then attention would fall on the decision to issue a clinical trial license on the grounds of preclinical data presented to MHRA. In other words, it was partly MHRA's own decision-making in respect of issuing a clinical trial authorisation that should have been under review. This might be taken at both a particular level (did it apply its own criteria reasonably in this case) and at a more general level (were its criteria and procedures reasonable). The Expert Scientific Group's report may not be subject to this criticism of possible conflict of interest. On the other hand, the ESG explicitly avoided any consideration of two essentially ethical questions. First, did the MHRA's risk assessment rightly balance the potential for harm against the likely scientific and clinical value of carrying out further research into this drug? And second, was the system of research governance and ethical review of clinical trials fit for purpose in terms of review of this kind of study, where a new drug of a new kind is introduced into human physiology for the first time?

There is much to say about this line of argument, which I do not intend to go into here. The construction of the issues in both the MHRA and ESG reports as being purely about scientific evidence and the rational assessment of risk is obviously something that social scientists, lawyers and others would be at least curious about! This construction is also included in the recent report into the operation of the UK NHS Research Ethics Committee system, which strongly recommended that RECs should *not* undertake review of scientific questions, but confine themselves to ethical ones. The Northwick Park case illustrates how difficult this actually is and how damaging it might prove. The REC at Northwick Park was put into the position of having to assume that if MHRA had issued a clinical trial certificate, then from a scientific and regulatory point of view questions of adequate preclinical testing and safety assessment were outside the REC's remit. But the REC has been criticised in the media, unfairly in my view, for its failure to check the preclinical evidence. Essentially, the REC was discouraged from fulfilling one of its substantive functions, viz., assessing whether the risk to participants was adequately estimated and controlled. Instead, the REC was left to assume that it had, and then to evaluate the more inchoate questions of whether it was justifiable to ask people to take this risk, whether their consent to participate was properly informed and was free from undue pressure due to financial inducement. Even with the exclusion of ethical and evaluative questions from the ESG report (which I do not think is intellectually defensible, but is common practice), the one thing the ESG and MHRA could usefully have

[2] Medicines and Healthcare Regulatory Authority *Investigations into Adverse Incidents During Clinical Trials of TGN1412* Available at: http://www.mhra.gov.uk/home/idcplg?IdcService=GET_FILE&dDocName=CON2023821&RevisionSelectionMethod=LatestReleased (Accessed 9-2-07)

done so far as the REC was concerned was to state that they acted properly in accordance with the guidance in force. As they were not charged with looking into this, and no one else has been given the job of doing so, the REC are left with a cloud over them. So – I would like to pursue that question a little further.

Instead of making an argument about the defects or otherwise of the official reports and their terms of reference, I would like to accept their conclusions at face value. I do not think this is a story of crooked researchers, inadequate regulation, or insufficient or misleading preclinical testing (although I could be persuadable otherwise). Instead I think this trial raises a more fundamental issue about what we can do to the bodies of humans in the name of medical, scientific and commercial progress, and how bioethics and human rights provide different models for thinking about this question.

Bioethics and Human Experimentation

There are essentially two ways a bioethicist would appraise a trial such as the TGN1412 trial. One way would be to seek to apply published guidelines to the trial, to see whether or not it complied with the principles and rules stated in such guidance. The other way would be to start from first principles. The advantage of starting with the guidelines is that they give a framework for analysis. The disadvantage (aside from the boredom which quickly sets in when reading such documents) is that a guideline-driven approach risks a narrow legalism, and obscures the extent to which ethical judgement is required even while applying the letter of the guidelines. In the TGN1412 case, even if we were satisfied that all published guidelines had been adhered to – essentially this was the finding of the two official inquiries – we might be left feeling that something of the ethical heart of the matter had not been brought to light. For instance, take paragraph 16 of the Declaration of Helsinki:

> Every medical research project involving human subjects should be preceded by careful assessment of predictable risks and burdens in comparison with foreseeable benefits to the subject or to others. This does not preclude the participation of healthy volunteers in medical research. The design of all studies should be publicly available.[3]

This is a central part of the Declaration, which is the principal ethical guideline issued by the World Medical Association to its member associations, through them addressing the worldwide medical profession about their responsibilities to their patients and to healthy volunteers taking part in research under their supervision. Notice that the language used is of careful assessment and comparison. The rest of the Declaration discusses the responsibilities of clinicians, mentions specific kinds of risk and vulnerable group that attract particular caution, and underscores the importance of informed consent. But this paragraph is at the heart of the matter. If the fundamental ethical challenge of research is that physicians and others with a moral responsibility to do no harm are required in the research setting to do things that may perhaps (and in some circumstances certainly will) cause some degree of harm. What paragraph 16 does is not to prescribe how to compare risks and

[3] World Medical Association. Ethical Principles for Medical Reearch Involving Human Subjects. (The Declaration of Helsinki). http://www.wma.net/e/policy/b3.htm (Accessed 12-02-07) (Emphasis added).

benefits, nor to proscribe certain risks (although elsewhere in the Declaration it is clear that the safety and welfare of the subject must take priority over the interests of science and society). Instead, it lays a responsibility on physicians and others to assess the risks and weigh them up against benefits (and elsewhere the Declaration requires researchers to have their protocols independently reviewed by an ethics committee). No objective standard or methodology is suggested. So instead, we are obliged, case by case, to evaluate the risks and benefits of research for each potential participant. While the Declaration prescribes certain questions to be asked, it can be rather unhelpful when it comes to suggesting how they should be answered, or what would count as a good or bad answer.

The three fundamental components of an ethical appraisal of human experimentation are: the consent of the individual participant (where they have the mental capacity to do give it); the appropriate balancing of risks and benefits to be faced by the participant; and the moral obligation of the researcher to safeguard the interests of the participant. If we turn to one of the other foundational documents of bioethics, report of the US National Commission for the Protection of Human Subjects in Biomedical and Behavioral Research (the Belmont Report, 1979), we find that three central principles of good research conduct were proposed: Respect for Autonomy, Beneficence, and Justice. These principles were presented as prima facie principles, each of which might on occasion outweigh the others (and indeed might be outweighed by other moral principles relating to concerns beyond the research setting itself). They are addressed to researchers, rather than to participants or society at large. And they are concerned with protection of the rights, interests, welfare and dignity of each human subject in research.

An outline of how these might apply to the Northwick Park trial is as follows. Although there is no prior reason to assume that Respect for Autonomy is the first principle among equals, it is consistent with liberal political philosophy and medical law and ethics to think that respect for the autonomous choice of the research participant is a necessary if not sufficient condition for participation in research. Respect for autonomy is usually translated into the form of requiring the informed and voluntary consent of the research participant. We might then ask of each participant – were they appropriately informed about the research, its purposes, methods and attendant risks? Were they mentally competent to make a decision? Were they improperly induced or otherwise coerced into participation? And in a sense we might stop there. We might argue that it is the research participant's job to decide, provided he or she has all the information she would need to make an informed choice, whether it is in his or her best interests, or consistent with his or her preferences and values, to participate.
Bioethicists would normally go a bit further, as the Belmont principles suggest they should. We need to determine whether the researchers have done all they can to control (perhaps to minimise) the risks posed in the research, whether what they are doing is worthwhile, and whether they are conducting the research in a professional manner, consistent with good practice in health and safety. Most people would stop there. In a sense the ethical review of research is designed to overcome a sort of "market failure" in research participation: participant and researcher are on opposite sides of an information asymmetry potentially adverse to the participant. Ethical review is designed to ensure that researchers conform to best practice, and to see that participants know all that they need to in order to make a good decision.

Some bioethicists would go a little further. They might be concerned that voluntary consent in conditions of full information might still lead to unfairness in the distribution of risk. The requirements of justice in research are complex, and deserve much more detailed discussion than I can give here. But for present purposes two different kinds of injustice might be central. First, we might be concerned about the form of injustice which is involved in failing to treat human beings as people with lives and values and inherent human dignity. A risk in some research is that people are seen as merely what in a military context might be called human matérielle. Rather than seeing consent as a process, requiring the engagement of researcher with participant on a basis of respect, we could see it as a mere authorisation to proceed, as in a commercial transaction between strangers. This would be a challenge to the essentially *medical* ethic of biomedical research. Justice in this sense is relatively rarely discussed in the bioethics literature, which, following the trend of most modern English-language moral and political philosophy is concerned largely with the second concept of justice relevant here, distributive justice. Distributive justice in research ethics is concerned with the fair distribution of risks and benefits among participants and non-participants. For example, are people unfairly excluded from participation? Or are those who participate selected from some particularly vulnerable group who may be less able to decline, or more at risk of the foreseeable harms, or less likely to benefit from the outcomes of the research than are other potential participants?

In the TGN1412 case, therefore, we'd be concerned with whether the risks were known, as far as they reasonably could be, minimised so far as was feasible, and justifiable in terms of the likely benefits to humankind which might flow from successful testing of the drug. We'd want to know if the participants were properly informed and neither vulnerable psychologically nor under pressure to participate. We'd want to know if the payment they were offered was reasonable, but short of an unfair inducement which might lead them to take risks which only a desperate person would take. We'd want to know if their selection was fair, and that they were not being exploited. Much of the practical work of bioethics in this context would be to answer these questions, and the theoretical work would be concerned with what would count as answers. For instance, for most mainstream bioethicists, the analytical framework that would come most naturally is the liberal approach to participation in civil society moderated by the harm principle. A very strong tendency in contemporary bioethics is to emphasise the role of free, rational choice, and to find ways to ensure that choice is as free and as rational as possible, and then to leave the choices actually made to the individual as sovereign. Most contemporary bioethics pays some lip service to questions of justice, but typically finds that these are most easily handled and operationalised by translating them into questions of ensuring that choices are autonomous. For example, most bioethicists would be troubled by a suggestion that a research project was somehow exploitative. Yet they would either say that if the person knew the terms of the deal and was autonomous then to take part or not is up to them so that barring participation on the grounds that the deal was exploitative would be unwarranted paternalism, or that the exploitative nature of the deal should best be understood as a sort of harm, or as evidence of a kind of externally imposed incapacity.

An illustration of this is the issue of paying healthy volunteers to take part in research. Most published guidance – including that of the BMA and the Royal College of Physicians – insists

that payments to research subjects may be "reimbursement" for legitimate expenses (such as time away from other work), but not be presented as, or amount to, "payment to take a risk". This can be parsed as a concern either with the voluntariness of a decision made under inducement; or that inviting someone to take a risk for payment would in a way transform the relationship between researcher and participant such that the payment would be a sort of license to harm the participant rather than a collaboration of equals. One might wonder at the naivety involved in thinking that they way to deal with potential exploitation in research is to lower the fee paid and to identify it with recompense for time off work rather than payment for taking a chance. And indeed more thorough-going liberal bioethicists have for a while now tried to discredit the concepts of exploitation and improper inducement. For this school of thought what matters is the quality of the consent, and the controls in place to minimise risk so far as possible consistent with the aims of the research.

In the case of the TGN1412 trial, assuming that the researchers had satisfied themselves and the regulators that there was no reason to expect serious harm from the new drug, and that each participant was both healthy and properly informed, and that compensation arrangements were adequate in case of disaster, then there was no reason not to proceed. This was a situation of free contracting between equals, admittedly involving some physical hazard, and some moral hazard in terms of possible participation for the wrong reasons (e.g., merely for the money). Indeed, once the individual's immediate interests are guaranteed through risk control and informed consent, the bioethical position is essentially that this sort of research is morally admirable in that it involves citizen participation in the advancement of medical knowledge for the common good. Some current commentators are arguing that there may actually be a social duty to participate in research, and that current research regulations are excessively concerned with risk control, instead of promotion of solidarity or public interest goals. The good biological citizen will use his or her freedom, through consent not merely as authorisation but actually as positive choice, to advance the common good through participation in research. A parallel argument with different emphasis is that the rational patient will participate in research in his or her own best interests, since in most cases the treatments used are used under conditions of genuine uncertainty as to their efficacy or safety: participation in a controlled trial is a way to get the best treatment in a sort of gamble with nature.

In summary, the essential feature of the bioethical approach is a sort of paradox. Bioethics begins as a way to spell out the duties of researchers to avoid harming research participants, but has become a style of thought concerned with seeing people as rational agents who can willingly choose to take risks or suffer harms, provided that they are given a convincing rationale for doing so. Within this framework, the TGN1412 trial poses no moral dilemmas at all: it is simply a tale of tragic misfortune and good intentions. And in a sense, this is where the two official reports ended up as well, albeit via a deliberate exclusion of ethical concerns from their remits. As I noted earlier, however, there is something odd about this conclusion. The evaluation of risk-benefit trade-offs is presented as a merely technical matter in the official reports, when it is a moral matter. But the moral language we have developed for discussing this sort of trade-off has efficiently transformed the moral matter into a matter of private choice. Bioethics - I contend – has obviated the need for an objective assessment of risk by substituting the good faith of researchers and the rational choice of the participants,

as mediated by the research ethics committees. An essentially subjective standard has replaced an objective judgement of right and wrong, fair and unfair. Various philosophical methods have been devised to try to close the circle and render these subjective determinations into objective ones by appeal to "reasonable person" standards or by use of casuistry to conform present debatable cases to past settled ones. But I suggest that we have arrived in research ethics at the position Marx argued classical economics had arrived at 200 years ago: objective value has been driven out by exchange value.

Something is clearly up. Surely we know that certain kinds of harms are objectively wrong, and no amount of contracting between reasonable people can overcome that? For instance, to kill someone for scientific purposes, even with their consent, cannot be justifiable? Had a TGN1412 volunteer died, and the risk of death had been disclosed to them, then how would consent have transformed that death from culpably wrong to merely regrettable? Surely if we approach the matter through a human rights framework, we will do better!

Human Rights and Human Experimentation: Clear as Mud

There are as many human rights approaches to human experimentation as there are bioethical ones, I suppose, but just as I sketched a sort of ideal typical version of "bioethics" for the purposes of this paper, I want now to sketch an ideal typical human rights approach. I will approach this through international human rights norms, rather than through legislation and case law, partly because there is so little of the latter. In passing we can note that the applicable legislation in the TGN1412 case would essentially be the Medicines Act (1968), the subsequent EC Directives and national regulations and amendments, and the Medicines for Human Use: Clinical Trials Regulations (2004), all of which must now be read in a way consistent (so far as is possible) with the Human Rights Act (1998).

To begin at the beginning. The Universal Declaration of Human Rights (1948) postdates the Nuremberg Code by more than a year, but makes no mention of human experimentation as a specific context of human rights violations or as a category of human rights violations itself. The preamble to the Declaration refers us to the "inherent dignity and … the equal and inalienable rights of all members of the human family", article 3 accords everyone "the right to life, liberty and security of person", and article 5 asserts that "no one shall be subjected to torture or to cruel, inhuman or degrading treatment or punishment". A close and motivated reading of these articles might find that participation in human experimentation could amount to violations of these values and norms. Giorgio Agamben refers in his thought-provoking book *Homo Sacer* to various means by which states may (and have) reduce those under their control to a condition outside human rights, according to which one is the subject of "bare life". One of his instances is the condition of experimental subjects in the Nazi death camps – but he also refers us to the situation in American prisons where (at least in the past) one could obtain remission of the death sentence, or reduction in the length of penal servitude, by agreeing to participate in human experimentation. A choice, he argues, which is no choice at all: the bare life one is subject of has become at the disposal of the authorities, for experiment, forced labour, or execution as they see fit.

To read the Universal Declaration this way might have some historical merit. But the defender of TeGenero and Parexel up at Northwick Park would point out that human experimentation as such does not necessarily require bare subjects, nor does it posit human participants as such. Domination and subjection has many modes, and if it clothes itself in the guise of experiment that does not necessarily show that human experimentation as such is compromised.

Turning to the 1966 International Covenant on Civil and Political Rights, we find article 7, which asserts that "no one shall be subjected to torture or to cruel, inhuman or degrading treatment or punishment. In particular, no one shall be subjected without his free consent to medical or scientific experimentation." Article 4, which defines a limited power by states to derogate from some obligations under this Covenant in situations of emergency, excepts article 7 (amongst others). There is nothing explicitly relating to human experimentation in the International Covenant on Economic, Social and Cultural Rights of the same year. Clearly this article of the ICCPR does engage with the Nuremberg Code, and aligns being the subject of human experimentation to torture, cruel, inhuman or degrading treatment. What relieves human experimentation from being identified with such treatment tout court is free consent. Reading this article in isolation, one could conclude that the wrong of unconsented experimentation is not the violence or harm done, but the lack of respect for autonomy. Yet it would surely be a forced reading of the article to propose that the harm makes no difference if the consent is forthcoming. The standard example might be pornography: consent to be represented for pornographic purposes may well not mean that the subject is not humiliated in some way by being so represented. Legal scholar Roger Brownsword and philosopher of law Deryck Beyleveld have argued that human dignity in human rights instruments is a dual concept relating both to the inherent worth of the individual and to the capacity of human individuals to be autonomous. Article 7 seems to elide the two conceptions of dignity. In the context of ICCPR as whole, however, it is clear that Article 7 principally engages State action, and mainly in the context of the treatment of prisoners. Arguably it does not bear on the private treatment of individuals in commercial or clinical or academic settings at their liberty. Yet the possibility that human experimentation could on occasions other than State actions against unfree subjects be the vehicle of significant violations of human rights or dignity is raised by Article 7. The troubling role of consent in relieving human experimentation of its immorality remains. On the one hand, it conforms human rights approaches to human experimentation to those we saw above in bioethics. But on the other hand, its insufficiency in the light of other human rights considerations might imply that inasmuch as bioethics ignores human embodiment, human vulnerability, and citizens subjection within modern states, bioethics falls short of the requirements of the preamble to the Universal Declaration of Human Rights in respect of dignity and equality of rights.

A number of human rights documents since 1966 have engaged with human rights and biomedicine, notably the Council of Europe's Convention on Human Rights and Biomedicine of 1997 and UNESCO's Universal Declaration on Human Rights and Bioethics of 2005. I do not propose to discuss these: I find that they do not significantly illuminate the existing substantive human rights in the UDHR, ICESR and ICCPR, and to the extent that they give more detail on human rights in, and in the light of, biomedicine they do so either by importing

bioethics norms (for instance from the Declaration of Helsinki) or by adverting to the troubled concept of human dignity. Instead, I want to suggest that we can get a bit further with human rights as a framework for thinking of the normative framework for human experimentation by putting it into a broader context.

The human rights approach to human experimentation is rightly concerned with the vulnerable human subject, and the ways powerful agents and interests can reduce the human subject to a docile body for experimentation. On the other hand, consent is seen as the expression of dignity and the will to self-determination which prevents this reduction, and renders "mere experimentation" into something like collaborative participation in scientific endeavour – of which, as ICESR article 15b reminds us, is something we all have a right to enjoy the benefits. So to make sense of the TGN1412 trial we come to a fork. We might argue that consent to participate in research of this kind cannot be free, and hence that participation in such research is engaged by ICCPR article 7. To get to this we might have to construct an argument turning on the sort of exposure to physical risk involved in the TGN1412 trial being a violation of human dignity to which no one could willingly consent. This seems an implausible approach, since what was at stake in TGN1412 was not exposure to a known and appreciable risk of death, irreversible illness or disability, but (we are assuming) the materialisation of an unexpected but devastating harm. Unless we are prepared to hold that all such research is a potential violation of Article 7, we prove too much by going down this road. So, alternatively, we might look elsewhere for potential violations of human dignity which do not depend on the role of consent in ICCPR article 7.

Concluding remarks: From patient to worker

I suggest we have three options. We might say that there is a violation of human dignity, but that it is not in taking part in experiments as such, but taking part in experiments for money. Then either there is a violation of human dignity involved in there being human beings who are so desperate for money that they will subject themselves to serious (in consequences is small in likelihood) physical risk in order to get it. This is to liken the situation of the participants in the TGN1412 trial to that of those who sell their organs for transplantation. Or, there is a violation of the so-called right to health involved in permitting (expecting?) people to put their health at risk, for money or other benefits in kind, for the development of (commercial) drugs. Or, there is a violation of ICESR rights relating to safety in the workplace and rights of participation in the labour force without exposure to undue hazard.

The first of these possibilities may have merit: there are a range of paid-for human activities which seem to involve violations of human dignity (dwarf throwing, for instance), and of which consent does not relieve the gravity. But, on the other hand, there is first of all the sense that the rights involved are not so important, or the violations not so serious, as the sort of "human rights" which Nuremberg was concerned to protect, for instance. And also there is controversy about whether the activities in question are so bad in terms of dignity violations that the restrictions of the liberty of the willing participants, in turn an arguable violation of their dignity-as-autonomy, are less serious in comparison.

The second of these possibilities I find unpromising. There is a bitter irony in asking people to endanger their health so that others may be able to get treatment to improve theirs. But in a wider field of vision, people endanger their health in all sorts of ways, in recreation and paid employment, for much less constructive ends. Besides which, the right to health is notoriously slippery and controversial. If we can find a more solid basis for normative controls on human experimentation, we should try to do so.

I think the third possibility – seeing the rights of healthy volunteers in human experimentation as directly or indirectly applications of labour rights – much more promising. What some may find unpalatable about this is that it would see participation in human experiments for money as a kind of work, and that the payment received would be precisely payment to take a risk, rather than reimbursement of expenses. From an institutional point of view it has a number of merits; not only are the rights of human experimental subjects supported by the UDHR and ICESR, they have their own international agency to look after their interests (the ILO) and they have a national regulatory framework which is sophisticated in terms of risk assessment and control – the Health and Safety Executive. Potentially this approach to the rights and welfare of experimental subjects would be much more effective than the rather problematic system of bioethics norms I described above. Yet some caution is required. I have concentrated exclusively on trying to identify and interpret the rights which are engaged by human experimentation in the case of TGN1412. In practice, how do we apply these rights in regulation? It is arguable that drafting regulations to realise these rights, and adjudicating disputes invoking these rights, will turn out to involve moral judgement – bioethical argument, even. The risk that we import the subjectified account of risk which has become established in bioethics into the human rights framework we intended to be a more solid bulwark against subjectivism is going to be rather hard to elude.