

Hard Paternalism and Clinical Research: Why Not

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ABSTRACT

Jansen and Wall suggest a new way of defending hard paternalism in clinical research. They argue that non-therapeutic research exposing people to more than minimal risk should be banned on egalitarian grounds: in preventing poor decisionmakers from making bad decisions, we will promote equality of welfare. We argue that their proposal is flawed for four reasons.

First, the idea of poor decisionmakers is much more problematic than Jansen and Wall allow. Second, pace Jansen and Wall, it may be practicable for regulators to uncover the values a potential research participant holds when agreeing to enter a research project, so their claim that we must ban such research projects for all if we are to ban them for poor decision-makers looks to be unmotivated. Third, there seem to be cases where the liberty to enter the sort of research project Jansen and Wall discuss is morally weighty, and arguably should outweigh concerns of egalitarian distribution. Fourth, banning certain types of research, which seem on the face of it to offer an unfavourable risk benefit ratio, would have unwelcome consequences for all clinical research, which Jansen and Wall do not recognize.

INTRODUCTION

Paternalism involves interfering with another's liberty of action for that person's benefit. Soft paternalism involves interfering with actions which are substantially non-autonomous: for example, restraining someone who is about to walk into the path of an oncoming car that he has not seen. Hard paternalism involves interfering with actions which are at least substantially autonomous: for instance, preventing someone who has thought long and hard about the pointlessness of life from killing himself. Hard paternalism is generally thought to be more morally problematic than soft paternalism, as it threatens to involve wrongful disrespect for the agent's autonomy,

insofar as it seems to treat the agent as lacking the appropriate moral status to be able to decide how his or her own life should go.

In a recent article in this journal, Jansen and Wall suggest a new way of defending hard paternalism in clinical research, and propose that research with an unfavourable risk benefit ratio (for example, non-therapeutic research exposing people to more than minimal risk) should be banned altogether.¹

Jansen and Wall's thesis relies on applying a general argument about hard paternalism and fairness advanced by Richard Arneson to the specific context of clinical research.² Arneson himself however aims simply to criticise Mill's blanket anti-paternalism and so does not attempt to sketch out any specific policy on restricting liberty. In this article we show that it is difficult to apply Arneson's ideas in anything like a straightforward way in the context of clinical research. We conclude that we are still a long way short of justifying hard paternalism on grounds of fairness especially in the kinds of case Jansen and Wall are most interested in, namely where terminally ill patients would wish to enter clinical trials which have an apparently unfavourable expected harm-benefit ratio.

Arneson argues that it is fair to allow paternalistic regulation as this is the only way we are able to correct some problematic inequalities in welfare. Arneson's argument presupposes a claim that Nozick once made from the libertarian direction, namely that *liberty upsets patterns*: the more liberty we allow citizens, the more difficult it is to ensure that our favoured pattern of distribution of goods will come about.³ Arneson contraposes Nozick's argument: on Arneson's view, if we care about egalitarian distributions of welfare, then we should be prepared to interfere with people's liberty to ensure that our desired distribution of welfare comes about. More specifically, if we refuse to regulate paternalistically, we thereby condone a situation in which certain inequalities in welfare are exacerbated.

In outline, Arneson's argument goes as follows. Inequalities in welfare result from allowing liberty of choice, because some people make poor decisions and fail to generate welfare from the opportunities open to them or even use their liberties to harm themselves, whilst good decision makers generate more welfare. On the assumption that those who are good decision-makers will tend to be those who are already well off, and those who are worse decision-makers will tend to be those who

¹ Lynn A. Jansen and Steven Wall. Paternalism and fairness in clinical research *Bioethics* 2009; 23(3): 172–182.

² R. Arneson. Paternalism, Utility and Fairness, reprinted in *Mill's on Liberty: Critical Essays*. ed. G. Dworkin. 1997. Lanham, MD: Rowman and Littlefield.

³ Nozick's point concerning how liberty upsets patterns however did not rely on some people making poor choices. Robert Nozick, *Anarchy, State and Utopia* (New York: Basic Books), pp. 160–4.

already badly off, giving citizens the liberty to choose will tend to exacerbate existing inequalities in welfare. Hence, a “ban on paternalism in effect gives to the haves and takes from the have-nots.”⁴

If we have reason to think that justice contains as a core part a commitment to equality of welfare, it follows that refusing to allow states to act paternalistically can be unfair. On Arneson’s view, we do not have to be committed to any single account of welfare or even a strictly egalitarian view of justice to see the force of this insight; we need only be convinced that a straight utilitarianism which is insensitive to how benefits are distributed is too narrow.⁵

JANSEN AND WALL’S ARGUMENT

Jansen and Wall use Arneson’s argument to make the case that a commitment to fairness requires regulators of clinical research to ban certain types of clinical research. They first argue that even where we are talking about mentally and legally competent adults making adequately autonomous decisions, there are reasons of fairness for preventing those who are for one reason or another likely to be poor decision-makers from making poor choices. They thus aim to use the argument to defend hard paternalism for poor decision makers in the regulation of clinical research.

While they claim not to defend any particular set of restrictions, they focus on cases of terminally ill patients and non-therapeutic phase 1 clinical trials of new drugs which “clearly and unambiguously” engage paternalistic concern.⁶ If paternalism is not warranted in these cases, they suggest, it would be hard to see where it would be. These are cases, they imagine, where the risks and expected benefits of a research project are such that it would be very unlikely that a good decision-maker who was self-interested would choose to take part in it. Good decision-makers who are self-interested, they suggest, will refuse to engage in risky behaviour under two types of circumstances. First, where taking the risk offers them no benefit, and the risk of harm is greater than minimal (call this ‘greater than minimal risk’). Second, where taking the risk involves potential benefits as well as potential harms, but the potential benefits to the risk-taker are outweighed by the potential harms (call this ‘an unfavourable balance of harms over benefits’).

⁴ R. Arneson. *Paternalism, Utility and Fairness*, p. 86.

⁵ We should note however that, the force of Arneson’s argument is somewhat blunted if we do not agree that welfare is the good that egalitarians should be trying to distribute equally. We tend to think welfare is an implausible currency for egalitarian justice, but we leave this fundamental disagreement with Arneson (and Jansen and Wall) on one side here.

⁶ *Ibid*, 173.

Jansen and Wall argue that in both these types of case the fairness argument justifies us in paternalistically protecting poor decision-makers from making bad choices by removing the option of their so doing. However, they further argue that we do not have any psychological methods which are sufficiently reliable at distinguishing those who are poor decision makers from those who are good decision-makers wishing to enter the project for altruistic reasons. Jansen and Wall conclude, apparently with help from Arneson, that as a result we will also need to restrict the ability of good decision makers to participate in such research projects given these difficulties in determining who is a poor decision maker. They argue that this infringement of liberty of the good decision makers is also justified by the fairness argument.⁷ Jansen and Wall allow that something important can be lost in so confining liberty. They argue, however, that not all liberties are equally important: some liberties are basic, whilst others are not. Where a liberty is non-basic our commitment to equality of welfare should take precedence. They further argue that the liberty to take part in research is a non-basic liberty, and it should thus cede ground to the importance of maintaining equality of welfare.

So, to recap the general form of Jansen and Wall's argument is as follows:

1. Some people are poor decision-makers in matters concerning their own welfare, whilst others are good decision-makers.

⁷ It is worth noting that there could be two distinct reasons for restricting choice here, both of which could be deemed egalitarian in a broad sense. First, we could be concerned about the absolute level of the people who are worst off; second, we could be concerned with the size of the gap between the best off and the worst off. (Within current debates in political philosophy, these views correspond to the views labelled prioritarian and egalitarian respectively). The first view would be restricted to preventing those who are already badly off from making themselves even worse off. On this view, if it were possible to protect the poor decision makers without restricting the liberties of good decision makers, this would be preferable, as the alternative would be 'levelling down'. The second view would suggest that there was a case for such levelling down: that is, restricting the options of the good decision makers in order to ensure greater equality of welfare, and not simply as an unavoidable by-product of a justified restriction of the options of the poor decision makers. Jansen and Wall suggest that the problem is one of *lack of ability* to separate the poor from the good decision makers, rather than that it would be unfair to allow the good decision makers to increase the welfare gap between them and the poor decision makers by making use of their liberty to enter potentially dangerous research projects. Hence we assume they take the first 'prioritarian' reading of the importance of equality of welfare. The distinction between equality and priority matters to Jansen and Wall's argument because it determines whether they need their premise about being unable to tell the difference between good and bad decision makers. If they are egalitarians, they do not. All they need to know is that, with liberty, poor do worse and good do better to want to take liberty away from everyone. If they are prioritarrians, they do not regard taking liberty away from the good decision makers as itself a good thing, so they have to justify it by saying it is the inevitable price of being unable to tell good from poor decision makers.

2. Those who are good decision-makers will tend to have higher welfare than those who are poor decision-makers.
3. Therefore allowing liberty of choice will tend to exacerbate inequalities in welfare. (From 1 and 2)
4. It is possible to identify some research trials as offering a poor risk-benefit ratio (in self-interested terms) for potential research participants. Specifically, non-therapeutic research carrying more than minimal risk is such a case.
5. Where a trial offers a poor risk-benefit ratio, it would be only poor decision-makers or altruists who would opt to take part in it.
6. It is impracticable to distinguish the altruists from the poor decision-makers. We are not able to reliably prevent the poor decision-makers from taking part, whilst allowing the altruists to do so.
7. Therefore we cannot both protect the poor decision-makers and allow altruists the liberty to make their own choices in these circumstances.
8. Therefore we face a trade-off between liberty and equality:
 - a) Our commitment to equality of welfare gives us a *pro tanto* reason to restrict the liberty of choice of poor decision-makers who would wish to take part in trials with a poor risk-benefit ratio.
 - b) Our commitment to liberty gives us a *pro tanto* reason to allow competent adults to make their own decisions in matters regarding their own lives.
9. Some liberties are basic and some are non-basic.
10. Basic liberties must be stringently protected, but non-basic liberties need not be.
11. The liberty to take part in research trials is not a basic liberty.
12. Where a liberty is not basic, it should be legitimately curtailed in the interests of equality of welfare.
13. Therefore the liberty to take part in research trials should be legitimately curtailed in trials with poor risk-benefit ratios in the interests of equality of welfare.

In the rest of this paper, we argue that some of the premisses of this argument are false, and hence that the argument as a whole is unsound. We first examine what makes for a poor decision maker in clinical research. We show that this is not nearly as straightforward as Jansen and Wall suppose and argue that their attempts to identify trials with a poor-risk benefit ratio face a problem. Next we argue that it is easier and more practicable than Jansen and Wall allow distinguish altruistically motivated people from people who are making poor choices given their values, and hence that premiss 6 appears to be false. We also explore premise 11 and argue that the liberty to take part in some of the clinical research Jansen and Wall would wish restricted is a very important liberty indeed and may be required by a proper respect for basic liberties. Finally, there would be radical and unwelcome implications for

banning the types of research they propose to ban, and so we ultimately question their conclusion that the liberty to take part in research should be curtailed in the interests of equality of welfare.

WHEN WOULD IT BE A POOR DECISION TO ENTER A CLINICAL RESEARCH PROJECT?

In this section we aim to put some pressure on the idea of poor decision-makers, as Jansen and Wall seem to adopt the term. We suggest that people with unusual values create a problem for Jansen and Wall. They must either allow that such people can be good decision-makers (and thus undermine the claim that there are trials which unproblematically have a poor risk-benefit ratio), or claim (with problematic illiberality) that such people are *ipso facto* poor decision-makers.

Does being a good decision maker require only making sensible decisions *given* your values, or does it also involve valuing the right things? If being a good decision maker requires only making good decisions given your values, then we would have to admit that many different orderings of values will be legitimate. In this case, there will be people with unusual or eccentric values who would agree to participate in projects which would seem to Jansen and Wall to have a poor risk-benefit ratio. However, these projects would not count as having a poor risk-benefit ratio for the person with unusual values, and hence we could not say that the person was a poor decision maker. For example, healthy volunteers may consent to phase 1 trials where there is no hope of therapeutic benefit at all in exchange for a monetary incentive. If what counts is the decisions one makes *given* one's values, then such people will not count as poor decision-makers. Moreover, if we adopt this reading of good decision-making, then the association between disadvantage and poor decision making which Jansen and Wall's account presupposes seems much less convincing.⁸ In this case, the claim that protecting poor decision makers from themselves is justified on egalitarian grounds will lack the intuitive plausibility that Jansen and Wall impute to it and as they do not present any empirical data it looks like a mere assertion.

The other option would be for Jansen and Wall to insist that good decision-making is to be defined substantively, as not only deliberating correctly given your values, but also holding the correct values. Whilst such a policy would indeed licence us in thinking that people with unusual values are poor decision-makers, it is difficult to reconcile this model with many of the presuppositions we have about policy making

⁸ For instance, given this account of good decision-making, valuing \$1000 more than risk to life and limb need not be poor decision-making if, given the rest of your life circumstances and priorities, taking such a risk is the best way to pursue your life goals.

in a multicultural liberal society.⁹ In particular, our legal standards for mental capacity explicitly allow that people can have values which are as bizarre as they like, so long as they judge in accordance with these values, understand the facts of the case, and are not coerced. Hence, many people who have mental capacity in a legal sense would be deemed poor decision-makers on Jansen and Wall's account. Jansen and Wall would thus be imposing a much stricter conception of decision making competence in the case of research than we do elsewhere.¹⁰

We can examine this problem in greater depth if we look at Jansen and Wall's example of the sort of case which they feel would warrant hard paternalism through general regulation:

[I]t may be helpful to have in mind a type of trial that clearly and unambiguously engages paternalistic concern. Imagine, then, a Phase 1 randomised control trial that offers no prospect for therapeutic benefit and imposes significant risk of harm to its participants. Such a trial, let us assume, promises to advance medical knowledge; and, let us further assume, there are people who are willing to consent to participate in it. Here an argument for paternalistic interference will apply, if it applies anywhere in clinical research. (*ibid.*, 173).

When Jansen and Wall give more detail, it seems that the envisaged trial involves terminally ill patients who may not, it is true, expect to benefit according to standard decision theoretic models, yet they may hold a strong hope of some, any benefit:

For example, suppose a proposed *early phase oncology trial* is disapproved by an institutional review board (IRB) because it fails to satisfy some paternalistically motivated ethical restriction designed to protect research subjects. (*ibid.*, 173: italics added)

By using this example of early phase oncology trials, we can infer that their focus is on terminally ill patients for whom no other treatment has worked. Is the hope of cure in such circumstances sufficiently unreasonable that we should make the substantive judgement that anyone who would consent to enter such a trial is a poor decision maker? It is of course true that hope of benefit could be based on a 'therapeutic

⁹ Moreover, even if we were able to identify the substantively correct values, it seems far from clear that these values would follow the standard distinction between therapeutic and non-therapeutic research in the way Jansen and Wall suggest.

¹⁰ There may be good reasons for treating research as requiring higher standards of decision making competence than other contexts. However, they Jansen and Wall do not provide any argument for this position. They simply state that there is only a non-basic liberty to participate in clinical research and that research is therefore different from other activities.

misconception' about the probabilities of benefit,¹¹ and furthermore that the patient might end up worse off than before. Indeed, there are examples where some Parkinson's patients were worse off from participating in a trial than had they declined.¹² However, if we adopt a view of decisionmaking which analyses the quality of a decision relative to the decisionmaker's values, then it is far from clear that we can assume that the decision participate is a poor one: these patients may be desperate, but they need not be irrational for wanting to try something new in the hope that it works for them.¹³ They may think, for instance, that they do not want to simply give up without trying every possible avenue. Or they may well feel they have nothing to lose and everything to gain by agreeing to take part. So long as the patient is lucidly aware of the slim possibility of improvement in his or her condition, and wants to take part all things considered, it seems problematically illiberal to brand such a person a poor decision-maker and refuse to allow them the possibility of making this decision for themselves.¹⁴

Jansen and Wall could acknowledge that people with unusual values might wish to enter trials with a cost-benefit ratio that most people would think of as unfavourable, without being irrational given their values. They might reply that there will nonetheless remain a problematic rump of patients who are very likely to make poor decisions given their values, and that we ought to protect these people from themselves on egalitarian grounds. However, given that Jansen and Wall think that it is not practicable to distinguish poor decision makers from altruists it is hard to see how they would assess the scale of any such problem. If what they are alerting us to is the mere possibility that people will make bad choices, then it is difficult to see how much weight to place on this concern.

We do not disagree with the thought that we should put in place restrictions to protect persons who do not reach a minimum level of decision making competence from harm in research. However, as we shall argue in the next section, it seems easier than Jansen and Wall allow to distinguish between sufficiently competent decision makers

¹¹ P.S. Appelbaum. Clarifying the ethics of clinical research: a path toward avoiding the therapeutic misconception. *Am J Bioeth* 2002; (2): 22–23.

¹² C.R. Freed et al. Transplantation of embryonic dopamine neurons for severe Parkinson's disease. *N Engl J Med* 2001; 344(10): 710–19.

¹³ Sarah JL Edwards. Restricted treatments, inducements, and research participation. *Bioethics* 2006; 20(2): 77–91.

¹⁴ However, at some stage we might think that what seems like admirable hope in the face of adversity becomes stubborn denial. We will not explore this question further here except to point out that even here the chances of cure in the eighth phase 1 trial a desperate patient tries may be no less slim than their chances in the first. An onlooker's assessment of a patient's hope or stubborn determination in the absence of evidence one way or the other may be more telling of the onlooker's psychological fatigue.

and others, and so the case for a blanket ban on certain types of research is weaker than they imagine.

DISTINGUISHING GOOD FROM BAD DECISION MAKERS

While Mill argued that the problem of limited and imperfect knowledge of the impact of restrictive policies on the welfare of individual citizens ought to lead us to abandon paternalism,¹⁵ Arneson seems to draw the opposite conclusion at least in standard cases.

Seemingly applying Arneson's thoughts, a key plank in Jansen and Wall's argument for banning research which would be consented to for self-interested reasons only by 'poor' decision-makers is that we cannot reliably separate good decision-makers who are altruistic from poor decision-makers. Hence while they acknowledge that altruism may provide as good a reason to take risks with oneself as any, they claim that it is too difficult to distinguish altruism from poor decision making reliably and because of this, if we wish to protect the poor decision-makers we must also prevent good but altruistic decision-makers from entering such trials.

We have three responses to this argument. The first, narrow response is that it is by no means clear that it is as difficult as they might think to reliably distinguish between altruistic and self-interested but 'poor' reasons for undertaking a risk at an individual level. From psychology, we already have standard tools and procedures which aim to do just this for interventions which are probably rather more risky than the maximum level of risk in research which ethics committees would be willing to tolerate.¹⁶ For instance, it is legally permissible in the UK to donate a kidney not only to a close relative but also a complete stranger who is not a blood relation – a donation which shows remarkable altruism.¹⁷ Here, more than anywhere it is important to be sure that the altruistic donor really understands what he or she is doing and genuinely consents to it. The general consensus (in the UK at least) is that we can do this with sufficient

¹⁵ See John Stuart Mill., *On Liberty*, in *Collected Works*, vol. 5, ed. J. M. Robson (Toronto and Buffalo, University of Toronto Press, 1977), p. 283, "But the strongest of all the arguments against the interference of the public with purely personal conduct, is that when it does interfere, the odds are that it interferes wrongly, and in the wrong place."

¹⁶ Notice that Arneson rests his claim on a slightly different ground to that one which Jansen and Wall make their claim. Arneson's point is not that it is psychologically difficult to assess individuals but that government cannot feasibly take into account every individual's decision making needs when making policy.

¹⁷ See the UK Human Tissue Authority's guidance on altruistic donation at http://www.hta.gov.uk/transplantation/organ_donation/altruistic_donation.cfm

accuracy to allow the altruists to do so, whilst denying those who appear to be making a rash decision from so doing.¹⁸

The second response is that clinical research may not warrant a *general* ban as Arneson might have thought of it even if we accept that hard paternalism for some is justified. A general ban may be imposed by regulation. However, doctors are already in a position to impose paternalistic constraints selectively on individuals on the basis of their decision making capacity. They can thus legislate for research participants' abilities for practical deliberation on an individual basis making the argument for a general ban fall away. A quick reading of Arneson may suggest that *any* restrictions must make 'broad rough classifications' and that no restriction can practicably be tailored to individuals. However, Arneson himself refers to the role and ability of doctors to 'legislate' on an individual basis and this seemingly passing remark about a non-standard case cannot be overlooked here. (p.100) Why impose a ban generally when the social arrangements are already set up in clinical research to accommodate the assessment of individuals by doctors? It is true that it may be less insulting for everyone to be stopped than for specific individuals to be told they are poor decision makers. But this would be true in all circumstances and so general paternalism would prevent all risky activities. It is also true that doctor-investigators have potentially conflicting interests which may mean that they are more inclined to recruit people despite their being poor decision makers. However, there are already systems of independent review and monitoring set up to ensure this potential conflict does not become actual without the need for a general ban.¹⁹

The third, wider response is that judgements of mental capacity typically play the role of demarcating the division between 'good' and 'poor' decision-makers in liberal societies.²⁰ Regulators set a threshold level of mental capacity such that those who are most vulnerable, i.e. the mentally non-competent, are protected by paternalistic constraints.²¹ Adults are presumed to be able to look after themselves unless shown

¹⁸ Clearly more research is needed here to better understand what drives people to consent to be altruistic organ donors, how to ensure people have thought about what they really want, and to gauge how often people regret having become a donor. But the fact that it appears to be feasible to do so in cases where the risks of getting it wrong are far greater than in the average research project shows that Jansen and Wall's assumptions need (at the very least) further empirical grounding. Of course, along with any such 'test', there will be the possibility of error.

¹⁹ Sarah JL Edwards. The Rationale for Research Ethics Committees. *Research Ethics Review*. 2009.

²⁰ In fact Arneson himself talks about a minimal requirement that agents not be 'feeble-minded or insane' (p.93) (at the same time as holding that above this minimum the government cannot tailor policy to individuals in standard cases), a point which Jansen and Wall do not acknowledge.

²¹ Note that non-competent adults are recruited into non-therapeutic research only when the research relates to the condition impairing their mental capacity and when it carries no more than 'minimal' or 'negligible' risk. See for example the UK Mental Capacity Act 2005 at

otherwise and these legal standards explicitly allow that people can have values which are as idiosyncratic as they like, so long as they judge in accordance with these values and they have a roughly coherent set of values such that their decisions could be understood by an onlooker. Mentally competent adults have absolute legal rights to refuse medical treatments – even those thought to be therapeutic or indeed life saving. Those who are mentally competent but make seemingly poor or unwise choices are not further protected by coercive measures unless their values are incoherent in which case they fall under provisions of Mental Health protection. Similarly, regulators do not typically restrict liberty in cases where poor decision makers generate less welfare than good decision makers in non-research contexts except in quite specific circumstances such as the sales of drugs, liquor, and prescriptions. Without evidence, it is impossible to say how many people might agree to take part in clinical research who really should not. The mere possibility that some may make a poor decision seems too illiberal a ground on which to remove the liberties of all who might want to take part. And many risky activities are readily available for all however good or bad their decisions.

The test of mental capacity, as with any test, may be fallible and we might think someone is mentally competent when they are not and someone non-competent when they are. English law assumes it is better to get it wrong and fail to protect a non-competent person (by thinking they are in fact competent) than it would be to get it wrong and prevent a competent person from pursuing their life goals (by thinking they are non-competent).²² In short, regulators in a liberal society typically rank liberty above protecting the most vulnerable.

<http://www.dca.gov.uk/menincap/legis.htm>. Importantly, though, therapeutic research must also relate to the condition impairing their mental function such that non-competent adults may be denied other expected benefits including therapeutic benefits unlike those who are mentally competent to consent. A trial of an investigational treatment for heart disease will not admit non-competent patients with heart disease. The vulnerable may thus be the ones suffering inequalities in welfare as a direct result of supposed paternalistic constraints.

²² We might try to match the degree of mental competence we require of a decision maker to the particular risks (and indeed benefits) associated with a research project. One difficulty is that the same person may be deemed competent to consent but not to refuse the same treatment or vice versa, which makes the very ability to exercise choice disappear. A similar problem arises in setting a threshold of competence for therapeutic research but not for non-therapeutic research involving more than minimal risk in that the only difference between the two from the person's point of view is what benefits they can expect to reap. The same person could be deemed competent to consent to something beneficial but not to refuse the same treatment and lose those benefits. There are additional problems with relating risk to competence such as smuggling in the very question we are interested in answering i.e. is it justified to override the patient's decision for paternalistic reasons? (See further, Allen E. Buchanan and Dan W. Brock (eds.) *Deciding for Others: The Ethics of Surrogate Decision Making*. Cambridge University Press 1990; Ian Wilks 'The Debate Over Risk-Related Standards of Competence', *Bioethics* 1997; 11: 413-26; Mark R. Wicclair, 'Patient Decision-Making Capacity and Risk', *Bioethics* 1991; 5:

The ready availability of legal capacity as a standard for separating ‘good’ from ‘poor’ decision-makers, which probably sets a higher standard than Arneson’s minimum, presents Jansen and Wall with a choice they do not fully confront. Either they should explicitly reject the liberal reliance on an assumption of adult capacity and support an across-the-board hard paternalism in cases where decision-makers are likely to make autonomous but ‘poor’ choices; or alternatively they could provide an account of what makes the context of research different, and why it is easier to justify hard paternalism in research than other contexts. One thing they might say is that the liberty to take part in clinical research is different in that it is a non-basic liberty. We now attempt to challenge this position.

THE LIBERTY TO TAKE PART IN CLINICAL TRIALS CAN BE BASIC

Jansen and Wall write “it seems clear that the liberty to participate in clinical research is not fundamental to autonomous agency in the same way as genuine basic liberties, such as the liberties associated with freedom of conscience, political speech or the liberties involved in pursuing a life plan. This is hardly a controversial claim. To our knowledge, no one has presented the liberty to participate in clinical research in such strong terms.” (ibid,180)

We agree that some liberties are more important than others, but we suggest that it is wrong to think that the liberty to take part in clinical research is always relatively unimportant. Health is important in its own right and for the exercise of liberty.²³ In some cases we may go so far as to think that without it a person’s fundamental freedoms are in doubt and the opportunity to restore or maintain health may become a very important liberty indeed. Some clinical research with patients who are terminally ill may provide such an opportunity.

Where a particular treatment offers a patient their only potential chance of benefit for an otherwise incurable disease then the liberty to avail him or herself of that treatment is a significant and important one, even if the trial appears to offer (to the outsider) a rather unfavourable risk-benefit ratio. At such moments, the liberty to enter the research project is of key importance to how the person conceives of themselves, and how they face their impending death. However, it is important to notice that the moral

91-104; Mark R. Wicclair. The Continuing Debate over Risk Related Standards of Competence. *Bioethics* 1999; 13(2): 149-153.)

²³ Daniels, Norman, 1990, “Equality of What? Welfare, Resources, or Capabilities?”, *Philosophy and Phenomenological Research* 50 (supp. vol.), pp. 273-296.

weight here attaches to the *access* to the treatment and not to participation in research *per se*. If we were able to offer the experimental treatment separately from offering it in a trial,²⁴ we would agree with Jansen and Wall that the liberty to have the experimental treatment within the context of the research trial (where presumably the person might be randomised to a control arm) was not as weighty. The liberty to gain access to a trial may thus be parasitic on the right to life and the right to be free from discrimination. But this does not make it relatively unimportant. On the contrary, the right to life is a fundamental right and any protection of it is also most important.

IMPLICATIONS OF A GENERAL BAN FOR CLINICAL RESEARCH GENERALLY

In his original paper, Arneson acknowledges that arguments for hard paternalism on grounds of fairness usually assume that the effects of such restrictions on those not subject to the restriction and those not consenting will be insignificant.

However, when applying the argument to certain clinical research, this assumption does not hold. A general ban on non-therapeutic research would have rather unwelcome implications for third parties as well as for those who are supposedly protected by the general paternalism. Non-therapeutic research is a necessary part of the process of clinical research. Without it, no therapeutic research would be possible and all medical advances would stop. Much of this research cannot be certified to be of no more than minimal risk. Hence banning non-therapeutic research which poses risks above the minimal would also mean preventing much therapeutic research and all the social benefits we associate with evaluating scientific advances in medicine.

As an example of this, all first-in-man trials are non-therapeutic in the sense that they are not expected or even designed to benefit the individual participant. Furthermore, it is impossible to say that any phase 1 trial carries no more than ‘minimal’ risk partly because there is no clinical data on which to base such a judgement and partly because this is precisely what phase 1 trials are designed to find out, i.e. what the maximum tolerated dose of a new possible treatment is in humans. Without the knowledge gained from phase 1, it is impossible to jump straight to phases 2 and 3 which are more often regarded as ‘therapeutic’ in the sense that any clinical benefits

²⁴ For example, the High Court in England and Wales ruled that it would be lawful for patients with vCJD to receive an experimental treatment called pentosan polysulphate despite the regulator having refused and with no rider about using the data for ‘research’ in the public interest. For more on this case, see Owen Dyer, “Family finds hospital willing to give experimental CJD treatment”, *BMJ* 2003;326(7379):8 (4 January).

of a possible new treatment are at least measured and compared with those of an existing standard or a placebo. So, a ban on non-therapeutic research would also rule out therapeutic research. This is a consequence we would not want to accept - at least without further argument - since it would halt the process of giving patients and doctors more information on which to base their treatment decisions in routine clinical practice and it would prevent both good and bad decision makers alike from reaping the benefits offered in therapeutic research, leaving everyone worse off. Moreover, material progress from research could help to redress the inequalities in welfare.

Jansen and Wall could respond to this problem in two ways. First, they could simply increase the level of risk that they think appropriate in non-therapeutic research, so that fewer non-therapeutic projects would then be ruled out. Second they could elect to count money for participation as a benefit, and thus bring non-therapeutic research under their more general decision-making model, whereby we ask if the potential harms outweigh the potential benefits for the participant, rather than simply looking at the level of risk. The obvious question for Jansen and Wall is this: if you want to prevent trials with an unfavourable risk-benefit ratio, why opt for bans rather than requiring improvements to the ratio? Offering monetary incentives are one way of changing the risk-benefit ratio.²⁵ While some people may not accept this approach to increasing the benefits research could offer, there may be others available such as extra health checks or care visits.

CONCLUSION

As liberal egalitarians, we are sympathetic to the motivating ideals of Jansen and Wall's argument. They are right to point out that equality matters, and that giving priority to liberty will often involve costs to equality. However, we are unconvinced by their current argument for banning research projects with a poor risk-benefit ratio. First, it seems more practicable than Jansen and Wall allow to determine the values on the basis of which a potential research participant wishes to enter a risky research project, so the claim that we must ban such research projects for all if we ban them for the poor decision-makers looks to be unmotivated.

Second, the idea of poor decision-makers is much more problematic than Jansen and Wall allow: if being a poor decision maker means making poor decisions *given your values*, then there will be many with unusual values who might agree to participate in projects which to Jansen and Wall would seem to have a poor risk-benefit ratio, without thereby counting as poor decision makers. If, however Jansen and Wall think

²⁵ See the classic defence of financial inducements in T. M. Wilkinson and A. Moore. Inducement in research. *Bioethics* 1997;11(5): 373–89.

that there are some substantive values which good decision makers hold but poor ones do not, then they will find it difficult to reconcile this model with a lot of the presuppositions we have about policy making in a multicultural liberal society.

Last, there do seem to be cases where the liberty to enter a research project is morally weighty, and should outweigh concerns with egalitarian distribution. Furthermore, if we ban the sort of projects Jansen and Wall suggest, we would inevitably ban research with a more favourable risk benefit ratio as an unintended consequence. We conclude that it is unnecessary and undesirable to curtail the liberty to take part in research in the ways that Jansen and Wall think it is.

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