The Inalienable Right to Withdraw from Research

By: Terrance McConnell

McConnell, Terrance. "The Inalienable Right to Withdraw from Research," *The Journal of Law, Medicine & Ethics*, 38.4 (2010), pp. 840-846. DOI: 10.1111/j.1748-720X.2010.00537.x

Made available courtesy of American Society of Law, Medicine & Ethics.

*****Reprinted with permission. No further reproduction is authorized without written permission from American Society of Law, Medicine & Ethics. This version of the document is not the version of record. Figures and/or pictures may be missing from this format of the document. *****

Abstract:

Introduction

Consent forms given to potential subjects in research protocols typically contain a sentence like this: "You have a right to withdraw from this study at any time without penalty" If you have ever served on an institutional review board (IRB) or a research ethics committee, you have no doubt read such a sentence often. Moreover, codes of ethics governing medical research endorse such a right. For example, paragraph 24 of the Declaration of Helsinki says, "The subject should be informed of the right.., to withdraw consent to participate at any time without reprisal." Similarly, section C of the Belmont Report says that subjects must be informed that they have the right "to withdraw at any time from the research" And in section 46.116 of the Common Rule (issued by the United States Department of Health and Human Services), it says that one of the elements of informed consent must include a statement that "the subject may discontinue participation at any time without penalty or loss of benefit to which the subject is otherwise entitled." (1) In each of these cases, there is no indication that the right is qualified in any way. There does appear to be a qualification in the first code of ethics for researchers, the Nuremberg Code, which says: "During the course of the experiment the human subject should be at liberty to bring the experiment to an end if he has reached the physical or mental state where continuation of the experiment seems to him to be impossible." (2) It is important to note, however, that the Code says that this is a reason to allow subjects to withdraw; it does not imply that this is the only reason.

Keywords: ethics | medicine | academic research | research ethics | research consent | informed consent | research methods

Article:

Introduction

Consent forms given to potential subjects in research protocols typically contain a sentence like this: "You have a right to withdraw from this study at any time without penalty" If you have ever served on an institutional review board (IRB) or a research ethics committee, you have no doubt read such a sentence often. Moreover, codes of ethics governing medical research endorse such a right. For example, paragraph 24 of the Declaration of Helsinki says, "The subject should be informed of the right.., to withdraw consent to participate at any time without reprisal." Similarly, section C of the Belmont Report says that subjects must be informed that they have the right "to withdraw at any time from the research" And in section 46.116 of the Common Rule (issued by the United States Department of Health and Human Services), it says that one of the elements of informed consent must include a statement that "the subject may discontinue participation at any time without penalty or loss of benefit to which the subject is otherwise entitled." (1) In each of these cases, there is no indication that the right is qualified in any way. There does appear to be a qualification in the first code of ethics for researchers, the Nuremberg Code, which says: "During the course of the experiment the human subject should be at liberty to bring the experiment to an end if he has reached the physical or mental state where continuation of the experiment seems to him to be impossible." (2) It is important to note, however, that the Code says that this is a reason to allow subjects to withdraw; it does not imply that this is the only reason.

The right of subjects to withdraw from research is thus usually interpreted as holding without qualification. Though this is not the same as saying that the right is inalienable, it suggests that it is. If a right is inalienable, that means that it may not be waived or transferred by its possessor. The view that the right to withdraw may not be alienated has recently come under attack, however, by Eric Chwang (3) andby Monique Spillman and Robert Sade. (4) These challenges come from two different directions. Chwang considers an example in which researchers want to test a drug that increases hemoglobin oxygen saturation.

> The drug is known to be safe, and the researcher just wants to test its efficacy. The proposed test is also safe: subjects take the drug, and then their pulse oximetry is measured via finger-clip for the next five minutes. However, suppose that the drug is so expensive that the researcher cannot afford to

> have any subjects remove the clip from their finger within this five-minute window, if statistical power is to be preserved. Thus, without a guarantee that subjects will not withdraw, the researcher will not be able to perform the study. (5)

In a case like this, Chwang thinks, subjects should be permitted to waive their right to withdraw from the study. Spillman and Sade, by contrast, discuss a case in which there is a potential threat to the public health. Xenotransplantation poses the risk of introducing a new or mutated infectious agent into the human population. The consequences of an unknown infection with a long latency period entering the human population could be horrible. To minimize this risk, many safeguards and restrictions have been recommended. One such precaution is that xenotransplant recipients should be subject to life-long surveillance, even if the xenotransplant is removed or fails. (6) Since xenotransplantation is experimental, Spillman and Sade believe that requiring subjects to submit to life-long surveillance effectively denies them the right to withdraw from research. (Later I shall suggest that the right to withdraw from such research is not best understood as the right to decline surveillance.) If either of these cases seems reasonable, then it seems that subjects should be permitted to waive their right to withdraw from research.

Rights and Obligations

Rights are normatively advantageous for their possessors. (7) One normative advantage provided is that rights put obligations on others, obligations that are owed to the possessors of the rights. When these obligations are in full-force, they indicate how the possessor of the right must be treated. But there may be situations in which those correlative obligations are suspended? If a right is overridden by a competing moral consideration, then the obligation correlative with that right has been defeated. If a possessor has forfeited his right, then the correlative obligation is suspended because of the possessor's wrongdoing. Of any given right, we can ask: Can that right be overridden? Can that right be forfeited? The answer to these questions can be different. For any given right, there is no reason to presume what its status is with respect to being overridable or forfeitable; in each case, it is a substantive normative issue.

A third way in which the duty correlative with a right might be suspended is if the possessor alienates that right. A right is alienable if it may be waived or transferred by its possessor. (9)

Waiver involves giving up a right voluntarily. Waiver is valid only if the possessor understands what she is doing and her choice is voluntary. When valid waiver occurs, the duty correlative with the right is suspended because of the possessor's consent. The possessor is giving another permission to do that which is normally forbidden because of the right. Transferring a right to another is a second type of alienation. The owner of property may transfer it to another by sale, trade, or gift. The new owner now has the right and the normative advantages therein. Waiver is unilateral; transfer is bilateral. Alienation is an act with normative efficacy. It either alters how others may treat the possessor of the right and/or it alters the obligations of the original rights-possessor.

But some rights may not be alienable. An inalienable right is one that may not be waived or transferred by its possessor. If a right is inalienable, the possessor's consent is not sufficient to make it permissible for others to infringe his right, nor may the possessor transfer the right to another. Possessors of inalienable rights lack the normative authority to alter the obligations correlative with those rights merely through consent. (10) As noted above, most codes of ethics have no provision for subjects to alienate the right to withdraw. Chwang and Spillman and Sade, by contrast, argue that a subject's right to withdraw should be seen as alienable; in particular, they maintain that this right may be waived by its possessor. If there were a compelling argument for taking as the default position that all rights are alienable, this position would be strong. But the traditional view is that some rights are inalienable. Moreover, as has been suggested elsewhere, arguments to show that all rights are alienable fail. (11)

Waiver to Secure Benefits

Chwang's pulse oximetry example is designed to show that in some cases "a beneficial study cannot be conducted without the waiver." (12) Indeed, Chwang asserts that researchers must have a "guarantee" that subjects will not withdraw or they will not be able to perform the study. Waiver of the right to withdraw from the study is one of the things necessary in order to produce the beneficial results for which the study aims. Chwang provides another example.

> Suppose, for example, that a prostate study
>
> requires intimate bodily access but (directly) benefits
>
> prospective subjects. Suppose further that...

> for financial reasons the study cannot go forward unless the researchers have a guarantee that their subjects will not withdraw. If I do not care about intimate access to my body, then I should be allowed to make this agreement and enroll, even if that enrolment requires the waiver of my right to withdraw. (13)

So in eases like these, the only ethically feasible means to the end is to allow the subjects to waive their right to withdraw from the research project.

When a right is alienable and the possessor alienates it, she alters the moral situation through her consent. In this case, waiving the right to withdraw creates for the possessor a new obligation, namely, an obligation to remain fully enrolled in the protocol. But notice that the mere fact that the agent has an obligation not to withdraw does not guarantee such an outcome; for agents do sometimes renege on their agreements. It is important in this sort of case that the obligation be enforced. The fact that enforcement of the obligation is necessary to achieve the desired end blurs the distinction between moral and legal rights, a distinction that Chwang is intent on retaining. (14) Moreover, enforcement of an obligation is a cost that must be weighed against any expected benefits, and that cost cuts at the heart of the argument.

Chwang's pulse oximetry case is a low-risk protocol. Indeed, what makes the example seem so compelling is that there is virtually no prospect of harm for the subjects. But reflection suggests that in low-risk protocols, little is gained in the way of compliance by having an enforceable waiver of the right not to withdraw. The likelihood of subjects completing this protocol is high; any gain in probability because of the threat of enforcement will be negligible. Suppose, however, that a protocol has some risks associated with it. Chwang's example of the prostate study is apt here since there may well be discomfort not properly anticipated by the subjects. Perhaps in a case like this the threat of enforcing a waiver will increase significantly participants' rate of completion. But threatening to enforce such alleged obligations will have social costs (to be spelled out in the last section of this article) that will likely outweigh the expected benefits. A dilemma is thus created. If achieving the benefit requires a guarantee of subjects' completion, as Chwang says, only a vigorous and unrelenting enforcement mechanism will be adequate. If, on the other hand, the goal is merely to increase the odds that more subjects complete the protocol,

then it must be conceded that these gains will have to be weighed against any expected losses that threats of enforcement create.

Waiver to Prevent Harm

Spillman and Sade argue that unless waiver is allowed in some cases, there will be a risk of public harm. Xenotransplantation poses the risk of introducing new or mutated infectious agents into the human population. If this were to happen, there could be a potential epidemic. To minimize such a possibility, the U.S. Public Health Service recommends life-long surveillance of such recipients and a mandatory autopsy at death. (15) Spillman and Sade believe that requiring life-long surveillance effectively denies to the subjects the right to withdraw from the research. This is doubtful, however. It is more plausible to say that what counts as withdrawing from such a protocol is denying to researchers permission to use any data collected from one's own case. Persons who have completed surveys and then wish to withdraw from the study usually have the option of directing that their data not be used. (16) Let us put this point aside, however, and grant that the requirement of life-long surveillance is a denial of the right to withdraw from research.

It seems clear that xenotransplatation cannot be allowed to take place unless the public health is protected as well as possible from a potential epidemic. And since recipients of xenotransplants--individuals who are both subjects and patients--are motivated in part by the desire to benefit themselves, it seems reasonable to require them to comply with long-term surveillance. Spillman and Sade say that disclosing to these individuals at the outset the need for such surveillance and eliciting from them a waiver of their right to withdraw from the protocol seems to be the best way to honor the principle of respect for persons while at the same time minimizing danger to the public. (17)

The public does need to be protected from the potential harm associated with xenotransplantation and that life-long surveillance of the subject-patients is necessary to achieve this end. Nevertheless it is doubtful that this establishes a ease for the waiver of the right to withdraw from research and it is doubtful that such an arrangement best honors the principle of respect for persons. First, in order for the waiver to be valid, it must be voluntary. But it is at least questionable that the subjects' waiver of the right to withdraw is voluntary if such waiver were a condition of receiving a xenotransplant. Patient-subjects opting for a xenotransplant are in dire straits; it is likely that no other therapeutic option is feasible. Agreement under such conditions is hard to give freely. Second, even if such agreement is given and is voluntary, it is not the

possessors' consent alone that justifies the enforcement of the surveillance requirement. If a protocol posed no risk to the public, it seems likely that few would approve of compelling subjects to continue their participation even if they had allegedly waived their right to withdraw. And in the case where there is a threat to the public, it is doubtful that a waiver is necessary.

To illustrate, suppose that a recipient of a xenotransplant had appeared to waive her right to withdraw. The waiver, however, was not valid, either because the person was unduly pressured or lacked the legal capacity to perform such an act. In this sort of case, it seems that the threat to the public alone will warrant enforced surveillance (even absent valid waiver). Respect for persons does require researchers to inform patient-subjects that life-long surveillance will occur (in the case of xenotransplantation). And knowing such information may prompt some not to opt for the transplant. But it is neither the act of informing the subjects nor their agreement that justifies pursuing surveillance even if the subjects object. Rather, in such a case, subjects' rights have been overridden. I am aware, of course, that a right that can be overridden may also be alienable. But the point here is that it need not be, and the overriding relationship alone explains the justification for surveillance.

Citing Patrik Florencio and Erik Ramanathan, however, Spillman and Sade claim that public health law as it stands in the United States, in the absence of an actual epidemic, is not sufficient to justify enforcement of surveillance. (18) As a result, their retort to the above criticism will be that without waiver of the right to withdraw from the protocol, there will be no legal justification for acting preemptively; officials will not be able to act until some damage is already done, and then it may not be possible to contain the harm. As a way of effecting this end, they suggest that we look at the idea of a Ulysses contract. Ulysses contracts, they note, are usually employed in the context of psychiatry. (19) Patients, while fully competent and in remission from their psychiatric disorder, can authorize their psychiatrist to provide certain treatments for that disorder should they subsequently need them, even if at that later time they refuse. Applied to xenotransplantation, potential recipients would agree to life-long surveillance as a condition of receiving the transplant. Spillman and Sade call this waiver of the right to withdraw from research and believe that it provides what is necessary to thwart potential harm to the public.

There are, however, three serious ways in which the analogy between Ulysses contracts in the context of psychiatry and those same contracts in the context where Spillman and Sade propose to use them differ. First, in the psychiatric ease, agents are limiting their future options for their own benefit. By contrast, in the xenotransplantation case agents' future options are restricted for the benefit of the public. Second, a Ulysses contract in the psychiatric context is presumably entered into freely by patients, and perhaps even initiated by the patients themselves. But under

the proposal of Spillman and Sade, individuals would not be eligible for xenotransplantation unless they agreed to give up their right to withdraw. And third, Ulysses contracts in the psychiatric cases take effect only after patients' decision-making capacity has been seriously compromised. In the cases involving xenotransplanration, however, the contracts will be in force even if the recipients are fully competent and opposed to the action. Thus in this latter case the patients' contemporaneous autonomy will be trumped.

There is an even more compelling reason for declining to adopt Spillman and Sade's proposal. They seem to assume that only if their proposal is adopted will society be justified in doing surveillance. But that need not be the case.

Let's suppose that Florencio and Ramanathan are correct in saying that public health law will not authorize enforced surveillance until an epidemic has begun. (20) If xenotransplantation is to proceed without endangering the public health, some change in the law will be necessary. Spillman and Sade want to do this by allowing the alienation of the right to withdraw; in particular, they suggest expanding the application of Ulysses contracts. But, as has been demonstrated, there are reasons not to do this. The values of respect for persons and self-determination, with which Spillman and Sade are justifiably concerned, can be honored through the process of informed consent. The only change needed, if any, is specific to xenotransplantation. The law can be changed to authorize selected physicians or public health officials to engage in surveillance of recipients even if they do not agree at that time. Minimal respect for autonomy, of course, demands that they be told this at the outset. So the informed consent document (and process) must include information about what will be done in the future if one is a xenotransplantation recipient, including life-long surveillance and an autopsy.

One reason provided earlier for why it is not the possessor's consent that warrants surveillance is that such consent is likely not to have been given freely (because of the recipient's desperate circumstances). But suppose that this factor is eliminated. Suppose that the procedure that poses a danger to the public is for a minor benefit. Because the benefit is minimal, there is no pressure to enroll. Even here measures to prevent the harm would be warranted in the absence of valid consent. To see this, suppose that patient-subjects' consent were compromised not by duress but by problematic competence. Surveillance would still be allowed precisely because of the importance of preventing harm. So in either case--when consent is not freely given or when the participant lacks the capacity to give consent--the individual's right not to be subjected to surveillance is overridden by the need to protect the public.

In Defense of Inalienability

If the right to withdraw from research is inalienable, then the possessor's consent alone does not authorize others to force her to continue to participate, nor does it give her an obligation to do so. This limits the freedom of individuals to enter into certain relationships.

Each of the arguments for the alienability of the right to withdraw from research considered here--the appeal to securing benefits and the appeal to avoiding harms--requires that the subject's waiver generates an obligation that others may enforce. For only with the power of enforcement can we be confident that the desired benefits will be obtained and the feared harms avoided. This is why the sharp distinction between moral and legal alienability on which Chwang insists (21) is not appropriate in this case. If the right to withdraw from research were morally (but not legally) alienable, then the subject's waiver would create an obligation but with no guaranteed right of enforcement. In such a case, subjects should certainly be informed that the obligation they have allegedly incurred will not be enforced. This will make it likely, one would think, that some will not comply with the requirement. But even if the creation of such a moral obligation were to result in fewer participants withdrawing from protocols, that is not enough, at least for the xenotransplantation case. For in that case, the magnitude of the potential harm requires universal surveillance. Nothing short of vigorous enforcement will suffice.

The specter of enforcing alleged obligations generated by the waiver of the right to withdraw from research demonstrates some of the costs of such a change. In many cases--especially in phase III clinical trials--researchers have difficulty securing the number of subjects needed. There are probably many reasons why people decline to participate in protocols. But it seems likely that if a waiver of the right to withdraw from research were possible and if the obligation incurred by such waiver were enforceable, then it would be even more difficult to recruit subjects. One especially important factor in this context is differential power held by researchers and their subjects. Once a protocol has begun, subjects have considerably less power than researchers. If in addition researchers had the power to prevent individuals from withdrawing from the protocol, then people would understandably be even more reluctant to enlist. Consider again the prostate study. Suppose that the participants agreed not to withdraw from the protocol, but now one man wishes to do so. Subjecting him to a forced examination, when that becomes known, will likely dampen the enthusiasm of many for medical research in general.

There are good reasons for both researchers and the law to endorse the inalienability of subjects' right to withdraw from research. As noted at the outset, most codes of ethics assign to participants in studies the right to withdraw, and that right is stated without qualification. While medical organizations may have many reasons to embrace such a right, concern about not discouraging participation and reluctance to override contemporaneous autonomy are two important ones. Securing waiver of the right to withdraw may ensure the completion of some projects, but it is a shortsighted strategy. If the public knows that even in some cases continued participation in research will be compelled, this is apt to make them less likely to take part. Society too has a stake in this. We all benefit from the successful completion of medical experiments. Anything that interferes with that end is prima facie undesirable. Some defenses of the inalienability of other rights also appeal to the public interest. Society does not allow the consent of a person by itself to justify killing him. This restriction protects innocent third parties from harm. (22) Similarly, a person can neither transfer her right to vote to another, nor can she obligate herself not to vote merely by giving her word to another. (23) None of these restrictions is based on paternalistically protecting individuals from their own foolishness. Rather, certain relationships are prohibited to prevent harm to the public. Yet another instance of this argument is that a patient's waiver of the right not to sue for malpractice is not recognized by the law because it is "against public policy." (24) My arguments not to allow the alienation of the right to withdraw from research are analogous to these.

One way of responding to this argument is worth considering. The difficulty in recruiting subjects is a mere contingency that may change. Indeed, for clinical trials examining potential therapies for fatal diseases for which there is no current treatment, there is competition to enroll; in these cases, the demand for access exceeds the supply. No good argument for the inalienability of the right to withdraw from research can hang by such a thin thread.

There are, however, replies to this criticism of the argument. First, only subjects themselves can say when pain or discomfort is too much to handle; such is the nature of subjective factors. As pointed out earlier, the Nuremberg Code demands that a subject be free to stop an experiment "if he has reached the physical or mental state where continuation seems to him to be impossible." The case for permitting subjects to withdraw from a protocol for this reason is strong, and it has wider implications than one might initially think. Others cannot determine accurately whether a subject has reached such a state. If only the participant himself can determine this, then he can cite that reason any time that he wishes to withdraw. Defenders of the alienability of the right to withdraw might think that this point is irrelevant for protocols with very low risk, such as Chwang's oximetry case. But because only the subjects themselves can say whether their discomfort is not tolerable, it is problematic to deny them the right to withdraw for this reason. This shows in another way why authorizing waiver of the right to withdraw from research is a

bad idea. In low risks projects, like Chwang's, waiver is unnecessary; few, if any, participants are likely to drop out of such a study. And the possibility that an obligation incurred by waiver of the right to withdraw would be enforced is apt to discourage many for agreeing to participate. For higher-risk protocols, where discomfort is more likely, it is hard to imagine compelling people to continue in the experiment in spite of their claims about discomfort.

There is a second reply to the criticism mentioned above. Even if the right to withdraw from research could be waived, that would not achieve the desired end. Normally alienation in the form of a contract involves a choice for the one who has alienated her right: either perform or pay damages. (25) By having such a choice, the alienator precludes what might be called self-enslavement. But if research subjects are given this choice, obvious problems emerge. For one, this will make many less likely to volunteer. Are people going to sign up for something even as simple as the pulse oximetry study if they know that they have to pay for dropping out early? In addition, even with such a choice, waiver of the right to withdraw from research will not ensure that the desired benefits will be procured. They will be achieved only if the subjects complete their participation. But if they have the option of paying damages instead, the desired end can still be thwarted. All that will have been achieved is an alteration of the participants' incentives. This problem is even more pronounced when the goal of waiver is to prevent harm (such as in the xenotransplantation case). For here if participants may pay damages instead of allowing continued surveillance, the threat of harm will be the same as it would be without the waiver. The difficulty in each of these cases can only be overcome if waiver is more restrictive than it is normally: performance must be the only acceptable option; payment of damages will not suffice.

Conclusion

Arguments for allowing alienation of the right to withdraw from research appeal to familiar moral principles: achievement of important benefits and prevention of significant harm. But neither argument is convincing. In the case of securing benefits, the goal can be achieved only if waiver implies that performance of the incurred obligation can be enforced regardless of the agent's wishes. This is a narrower than usual understanding of waiver; more importantly, however, even the threat of enforcement of such an obligation would likely discourage participation in clinical trials. In addition, waiver in low-risk protocols is unnecessary, and waiver in high-risk studies is hard to justify. Concerning the case of preventing harm, the costs of enforcement would be equally great. In addition, the end (ongoing surveillance of recipients of xenotransplants) can be achieved by specific legislation to that effect (justified by appeal to public health) accompanied by adequately informed consent. Waiver of the right to withdraw is unnecessary; and if it were implemented, its overall impact is likely to be negative.

Since the construction of the Nuremberg Code, conventional wisdom has portrayed the right to withdraw from research as inalienable. In this case, conventional wisdom should be followed.

Acknowledgements

I have benefited from the extensive criticisms of Eric Chwang. I also thank Heather Gert for her helpful comments. An earlier version of this paper was presented at the University of Minnesota (October 2009) and at a meeting of the Association of Practical and Professional Ethics (March 2010). I thank members of those audiences for their suggestions.

References

(1.) These documents are reprinted in E. J. Emanuel et al., eds., Ethical and Regulatory Aspects of Clinical Research: Readings and Commentary (Baltimore: Johns Hopkins University Press, 2003): at 31, 36, and 46, respectively.

(2.) Id., at 29.

(3.) E. Chwang, "Against the Inalienable Right to Withdraw from Research," Bioethics 22, no. 7 (2008): 370-378.

(4.) M.A. Spillman and R. M. Sade, "Clinical Trials of Xenotransplantation: Waiver of the Right to Withdraw from a Clinical Trial Should Be Required," Journal of Law, Medicine U Ethics 35, no. 2 (2007): 265-272.

(5.) See Chwang, supra note 3, at 370.

(6.) See Spillman and Sade, supra note 4, at 266-268.

(7.) L.W. Sumner, The Moral Foundation of Rights (New York: Oxford University Press, 1987): at Chapter 2.

(8.) T. MeConnell, Inalienable Rights: The Limits of Consent in Medicine and the Law (New York: Oxford University Press, 2000): at 5-7.

(9.) Id., at 8-11.

(10.) This account is not stipulative. For a defense, see id., at 12-14 and 18-19. See also, Black's Law Dictionary, 8th ed. (St. Paul, MN: West Publishing, 2004): at 1348; A. T. Kronman, "Paternalism and the Law of Contracts," Yale Law Journal 92, no. 5 (1983): at 775; and S. Rose-Ackerman, "Inalienability and the Theory of Property Rights," Columbia Law Review 85, no. 5 (1985): at 931.

(11.) See McConnell, supra note 8, at 24-31.

(12.) See Chwang, supra note 3, at 374.

(13.) Id., at 375.

(14.) Id., at 371-372.

(15.) See Spillman and Sade, supra note 4, at 266-267.

(16.) Once a survey has been completed, one might wonder what further interests of subjects could be implicated. To cite just one possibility, subjects may have developed moral objections to the study and not wish to be complicit in any way with such a project.

(17.) See Spillman and Sade, supra note 4, at 269.

(18.) Id., at 269. See also, P. S. Florencio and E. D. Ramanathan, "Legal Enforcement of Xenotransplantation Public Health Safeguards," Journal of Law, Medicine & Ethics 32, no. 1 (2004): 117-123.

(19.) Id., at 270.

(20.) There may be reason to doubt this, however. See L. O. Gostin, Public Health Law, 2nd ed. (Berkeley, CA: University of California Press, 2008): at 400-404, for a discussion of when compulsory screening and conditional screening are justified.

(21.) See Chwang, supra note 3, at 371.

(22.) See McConnell, supra note 8, at 83-85.

(23.) Id., at 12 and 52.

(24.) E. Menikok and E. P. Richards, What the Doctor Didn't Sap: The Hidden Truth about Medical Research (New York: Oxford University Press, 2006): at 45, arguing that a patient's waiver of the right not to sue for malpractice is not recognized by the law because it is "against public policy."

(25.) See Kronman, supra note 10, at 778-779.