

THE UNIVERSITY OF TEXAS AT SAN ANTONIO, COLLEGE OF BUSINESS

Working Paper SERIES

Date May 1, 2013

WP # 0031MGT-582-2013

You Might Not Have Access...

**Pepe Lee Chang
Department of Management
University of Texas at San Antonio**

Copyright © 2013, by the author(s). Please do not quote, cite, or reproduce without permission from the author(s).

Pepe Lee Chang
University of Texas at San Antonio

Forthcoming 2013 in *Theoretical and Applied Ethics Journal*

ABSTRACT

You Might Not Have Access...

In “You Get What someone Else Will Pay For,” Deborah Barnbaum provides two arguments for her view that what ought to be included in future informed consent documents for clinical research participants is the anticipated future cost of the drug being tested, were that drug to become available for future patients for whom that drug is indicated. In this paper, I will argue that although Barnbaum’s intentions are commendable, she has not provided sufficient reasons to require the future cost of the drug as relevant information for informed consent, and so it need not be included in the informed consent document. What I believe to be Barnbaum’s underlying concern is the potential for research sponsors to unfairly benefit from and exploit research participants as a result of an existing power imbalance within this relationship. Ultimately, although Barnbaum’s goal is a worthy one, I will argue that to achieve this goal, research sponsors do not need to include the anticipated future cost of the drug, as she argues, and that perhaps they should not, since including this information could lead to more harm than good. I argue that all that is needed for informed consent is a statement that indicates that research participants *might not* have personal access to the drug were it to pass the trial and reach the market.¹

Keywords: Informed Consent, Ethics, Research Participants, Autonomy
JEL: I11, I18, I19

¹ **Acknowledgements:** I would like to thank Diana Buccafurni and Chris Herrera for helpful comments on earlier drafts of this paper. This research was supported by a Summer Grant provided by the University of Texas at San Antonio.

Pepe Lee Chang
Theoretical and Applied Ethics Journal
Forthcoming 2013

You Might Not Have Access...

In “You Get What someone Else Will Pay For,” Deborah Barnbaum provides two arguments for her view that what ought to be included in future informed consent documents for clinical research participants is the anticipated future cost of the drug being tested, were that drug to become available for future patients for whom that drug is indicated. Barnbaum believes that having this information could be an important factor for potential research subjects in deciding whether to participate in clinical trials (Barnbaum, 2011). If she is right, then it seems correct to say that the predicted future cost of the drug should be considered important information and that it should be included in the informed consent forms, that is, if we really are concerned with participants making autonomous and informed decisions.

In this paper, I will argue that although Barnbaum’s intentions are commendable, she has not provided sufficient reasons to require the future cost of the drug as relevant information for informed consent, and so it need not be included in the informed consent document. Barnbaum begins her paper with two arguments. The first she calls “the argument from justice” and the second “the argument from disclosure of risks and benefits.” For the remainder of her paper, Barnbaum defends her view by replying to three objections she has already encountered from her critics. To begin, I will present a brief explanation of her two arguments and the objections she provides. Then, I will argue that Barnbaum has not given due consideration to the criticisms provided by her objectors. What I believe to be Barnbaum’s underlying concern is the potential

for research sponsors to unfairly benefit from and exploit research participants as a result of an existing power imbalance within this relationship. Barnbaum's hope is that becoming aware of the anticipated future cost of the drug will motivate dialogue between the two parties. This will enable the research participants to gather more information from the research sponsor, thus moving one step closer to balancing the power between them.

Ultimately, although Barnbaum's goal is a worthy one, I will argue that to achieve this goal, research sponsors do not need to include the anticipated future cost of the drug, as she argues, and that perhaps they should not, since including this information could lead to more harm than good. If I am right, Barnbaum's requirement will turn out to be not only unnecessarily stringent, but a requirement that could end up causing harm, in which case she will need to reconsider her argument for requiring research sponsors to include the anticipated future cost of the drug as relevant information for informed consent forms. I argue that a far less stringent requirement, which I believe will produce the dialogue Barnbaum hopes for, is to require, in the informed consent form, a statement that indicates that research participants *might not* have personal access to the drug were it to pass the trial and reach the market.

Barnbaum's "argument from justice" is straightforward as she presents it. When researcher sponsors are capable of minimizing or preventing possible exploitation of research participants, it is unjust for them not to do so. Barnbaum believes that the future cost of the test drug is information that can affect whether a person decides to participate in the clinical trial. According to Barnbaum, knowing the predicted future cost of the researched drug, were it to pass the clinical trial, may allow research participants to avoid, or at least undermine, attempts by research sponsors to exploit their vulnerability for future profits. Her aim is to prevent situations where a participant unknowingly contributes to the approval of a drug that more than

likely will be financially out of reach for themselves or loved ones as patients. Barnbaum is requiring research sponsors to satisfy the argument from justice by disclosing the future cost of the tested drug in the informed consent form so that participants have the relevant information to avoid being used as a mere means for the profit driven ends of the research sponsor. Barnbaum reminds us of the moral outrage that accompanied the AZT African/Thai trials where impoverished people were being exploited to benefit corporations, since the research participants would never be able to access the potentially life-saving drugs that were being tested on them² (Barnbaum, 2011).

In addition to the “argument from justice”, Barnbaum provides an “argument from disclosure of risk and benefits.” People have different reasons for participating in a clinical trial. According to Barnbaum, people need to have the right information for determining whether the cost of participating is worth the benefit they hope to achieve by doing so. Barnbaum’s view is that the future cost of the drug being tested is important information to have so that the potential participant can determine for themselves if the cost of participating in the clinical trial is worth the benefits produced by aiding in the approval of the drug. According to Barnbaum, the participant needs to know what the research sponsor plans to charge for the drug since the cost of a new drug can greatly influence its accessibility and units sold. This means that being informed of the future cost of the drug is necessary for calculating the anticipated benefit to potential patients.

² It has been suggested to me that it is important to distinguish between research participants who might not have access to the drugs in the future but will need them and research participants who may be cured from the tested drug, in which case, they are less likely to benefit from that drug in the future. I take the comment to mean that in the former circumstance, research sponsors are being unjust, as Barnbaum argues, while in the second case, the research sponsors are not being unjust and may be helping the research participants improve their quality of life and extend their life span. This latter circumstance would be considered a great benefit rather provided by the research sponsors rather than unjust exploitation.

Barnbaum's second argument expands on her first in that she thinks that all information that could prevent or minimize exploitation of research participants needs to be considered relevant information for informed consent. And since her first argument concludes that knowing the future cost of the tested drug could do just that, she believes she has also shown that this information is "crucial" information for informed consent (Barnbaum, 2011, p. 28). Given Barnbaum's argument, then, the predicted future cost of the tested drug ought to be included as relevant information for informed consent.

Barnbaum's two arguments are symbiotic since what counts as relevant information, in some sense, can be determined by how the information could affect the research subject's decision to participate in the clinical trial. Her point is that having information that could undermine the potentially exploitative intentions of researcher sponsors makes disclosing the future cost of the drug very relevant for the informed consent of the research participant. Barnbaum relies on the argument from justice to establish this relevance. This means that if it can be shown that omitting the future cost of the drug in the informed consent document does not violate "the argument from justice", then it can also be shown that omitting the future cost of the drug does not omit relevant information for informed consent.

That said, Barnbaum acknowledges and attempts to resolve three objections to her requirement of disclosing the anticipated future cost of the tested drug to research participants, for the sake of justice. First, not all companies will have the information in question, that being the future cost of the drug, so this requirement violates the "ought implies can" rule. In other words, the objection is that Barnbaum cannot require research sponsors to provide information that they do not have. Second, even if this information were to be included in the informed consent forms, it may not be understood by the research participant. Third, it is not always the

case that the future cost of the drug will be relevant to the research participant, in which case excluding this information will not always lead to a violation of justice. Consequently, Barnbaum's argument to mandate a general requirement to include the anticipated future cost of the drug for all informed consent forms, for the sake of justice, is unreasonable.

Barnbaum's response to the first claim is that it is simply false. She claims that pharmaceutical companies do indeed have an anticipated future cost of the tested drug that can and should be included in the informed consent forms. Her responses to the last two objections are equally as quick and dismissive. According to Barnbaum, as long as there is a *possibility* that having the knowledge of the cost of the future drug may be understood and relevant to the research participant, it should be left up to the research participant to decide if it is indeed so; the researcher sponsor has no business making this decision for the research participant.

Barnbaum depends heavily on the force of "the argument from justice" to reach her conclusion (Barnbaum, 2011). As previously stated, Barnbaum is motivated by preventing Big Pharma and biotech companies from unjustly exploiting the poor for their own benefit, and she is utilizing the informed consent form as a tool for research participants to avoid unknowingly and unwittingly contributing to their own exploitation, and the exploitation of future patients in need of the drug. Barnbaum's has attempted to prove her point forcefully by reminding us of the AZT African/Thai research subjects. However, it is important to recognize that not all trials where research participants may not be able to obtain the drug in the future are comparable to the AZT African/Thai trial, since most of these trials are not similarly situated.

There are several different factors that may distinguish one clinical trial from being unjustly exploitive from one that is not, even if in both trials the participants may not personally be able to afford the drug. For instance, whether the trial takes place in a developed, versus an

under-developed or undeveloped country can be an important factor in determining whether or not the participants legitimately can consider themselves as being unjustly exploited. Social infrastructure and support needs to be considered and acknowledged if accusations of exploitive behavior are to be deemed legitimate (De George, 1994). To assume that all cases where participants may not have financial access to the drug are analogous to the AZT African/Thai trial is somewhat problematic.³ And since most of the force of Barnbaum's argument from justice depends on this analogy, it follows that her argument from justice also is somewhat problematic.

The AZT Africa/Thai clinical trial is considered an extreme case of exploitation for many reasons, one being that the participants would have had absolutely no access to the drug were it to be proven effective and available on the market. Some consider the research participants to have been used merely as a means to an end by the research sponsors. In a developed country, where social and government assistance is the status quo, the inability for research participants to access the drug in the future is not similarly situated because in developed countries attaining the drug may not be futile. Given that they are not similarly situated, these clinical trials should not be subsumed into the category of unjust exploitation of research participants. As a result, not all cases will require disclosing the future cost of the drug as a means to achieving justice. Exploitation is a strong word and immediately conjures up behavior that is intuitively and in most cases knowingly immoral and unacceptable, and should be reserved for cases that sufficiently warrant such a judgment.

³ For instance, whether research sponsors are being exploitive could depend on factors having to do with a country's institutions and infrastructure or a research participant's special circumstances or personal concerns (a need for the drug only once, relatives' access to the drug, future patients' access to the drug, etc.). The point is that *why* future access would or would not matter to the research participant is more relevant than merely having no future access to the drug.

That said, it would make sense that Barnbaum's critics may not be convinced by her argument from justice since they would not accept the assumption that research participants actually are being exploited in which case they would not accept that principles of justice are being violated. Consequently, Barnbaum's reliance on her argument from justice does not provide the persuasive punch she needs to carry her argument through.

Overall, I do not believe that Barnbaum has given due consideration to the full force of her critics' objections. At the clinical trial phase, the future cost of the drug is predicted based on a speculated supply and demand curve. Predictions are unreliable and will more than likely always be vulnerable to manipulation (Chang, 2006). Claims made about predicted cost that are themselves based on a predicted supply demand curve will not be reliable. Since most, if not all, anticipated future costs will be predictions, if the disclosure of the future cost of the drug is required for informed consent, there is nothing to prevent pharmaceutical companies from predicting low for their own advantage (Angell, 2004). This means that even if Barnbaum is right about drug companies having an estimated price point for a new drug, its speculative nature will still be problematic if we want to require that the future cost of the drug be included as crucial information for informed consent. This is especially true if Barnbaum is right that this information will influence the decision of whether to participate in the clinical trial.

How the future cost of the drug is predicted, and what that number really means, may not be understood properly by the research subjects, and in some cases, this information may be *misunderstood* which means that including it in the informed consent document could do the opposite of what Barnbaum hopes. If the future cost of the tested drug is indeed a prediction, the most that should be incorporated into the informed consent form is that the research participant

might not be able to access the drugs if it were to pass the clinical trials⁴. Ultimately, this part of the information is all that the research participant would need to understand in order for it to count as relevant information for including it in informed consent documents.

One important requirement of informed consent is that the information provided must be understood in order to be relevant, and not the other way around (O'Neill, 2002). For example, suppose that Richard, a patient who has been diagnosed with serious health condition, must now choose which treatment to pursue. Richard relies on Dr. Vasquez to provide him with the relevant information to make an informed autonomous decision. If Dr. Vasquez bombards Richard with statistics and outcome probabilities that he will not understand, then Richard will not be able to translate that data into relevant and meaningful information to help make decisions for his own personal life goals.

It is important to recognize that too much information in the informed consent form can be just as misleading and harmful as too little information. If the future cost of the drug actually does affect the research subject's decision to participate in the trial, it must be clear whether the influence on the participant's decision is due to understanding, misunderstanding, or lack of understanding the disclosed information. It is premature and naive to assume that any type of influence on the research participant is due to fully understanding the proposed additional information and this would be true of any information that is up for consideration as crucially relevant for inclusion in the informed consent form. People frequently make decisions regarding whether or not to participate in activities that are based on misunderstanding or lack of

⁴ To be clear, I use the term "might not have access" as shorthand for a more inclusive statement in the informed consent form that would address multiple circumstances for lack of access to the future drug. Research patients could fail to have access due to inability to pay for the drug, countries where importing such drugs are unrealistic, countries whose social programs only provide older cheaper drugs that are favored over new possibly more effective drugs, etc.

understanding rather than understanding. If this is true, then Barnbaum's critics have a valid point which needs to be taken seriously and not so quickly dismissed. Research participants may not understand what the anticipated future cost of the drugs means to *them*, and this is true especially if that cost is a prediction provided by the research sponsor. Not only is it possible that this information may not be helpful, it may turn out that this information may be harmful. Recall Dr. Vasquez and her patient Richard. If Dr. Vasquez does not verify that Richard understands the provided statistics and outcome probabilities correctly, Richard could translate the information in a way that leads him to make the wrong choices for his own life goals.

As previously stated, the only meaningful component of including the future cost of the drug in the informed consent documents, for Barnbaum's purposes, is that the drug might not be accessible to research participants in need of the drug if it were to pass the clinical trials. Barnbaum wants to ensure that research participants are not being exploited for the benefit of the research sponsor. She wants to encourage dialogue between research participant and research sponsor, and she believes that the requirement of disclosing the anticipated future cost of the tested drug to the research participant will do just that. However, to address Barnbaum's concerns, all that needs to be included in the informed consent document is that research participants might not have access to the drug even if they were to need it; the participants do not necessarily need to know the actual or predicted future cost of the drug.

In regard to her critics third and final claim that "information about future costs is not relevant to the participant, unlike information about current risks and costs" (Barnbaum, 2011, p. 30), Barnbaum responds by asserting that only the research participant can decide what is relevant, and so *all possibly* relevant information should be incorporated into the informed consent form. However, if we follow this argument to its conclusion, it is seems reasonable to

say that requiring the disclosure of all “possibly” relevant information in the informed consent document will require including far too much information, which can either be helpful or harmful to the research participant. Even further, Barnbaum asserts that the future cost is in fact part of the risk/benefit profile of the drug being tested. Once again, even if she is correct that this information is part of the risk/benefit profile, the only part of that information that is relevant to the potential research participant is that she/he might not have access, that their family members might not have access, or that future patients might not have access to the drug were it to pass the clinical trial.

Barnbaum is right to be concerned with informed consent and her attempt to minimize opportunities for pharmaceutical and bio-tech companies to exploit research subjects is a worthy project. She wants research participants to be aware that they (as well as future patients) may not have access to the very drug(s) being tested on them. By drawing attention to the informed consent form, it seems that Barnbaum’s hope is to prevent research subjects from unknowingly contributing to their own exploitation or that of future patients, thereby unknowingly and unwittingly contributing to unequal access to healthcare. However, her claim that knowing the future cost of the drug being tested is, in fact, crucial to a research participant having informed consent is problematic.

As I have argued, to satisfy Barnbaum’s concerns, it is not a necessary requirement to include the predicted future cost of the drug in order to deter exploitation and to motivate dialogue between the research participant and the research sponsor. All that needs to be disclosed in the informed consent form is the claim that research participants *might not have access* to the drug being tested on them⁵. For pharmaceutical companies and research sponsors,

⁵ For a more specific example, Barnbaum should settle for a statement resembling the following: “...you or other patients in similar circumstances, might not have access to this drug in the future due to its likely cost.”

this alternative requirement for informed consent may be an easier pill to swallow than Barnbaum's requirement of including the future cost of the drug in the informed consent document. At the very least, by adapting her view to this more general requirement, Barnbaum can account for and perhaps avoid the objections given by her critics, allowing her to move one step closer to addressing her concerns regarding informed consent, justice and minimizing opportunities for research sponsors to exploit research participants for the sake of profit.

References:

Angell, M. (2004). *The Truth About the Drug Companies: How They Deceive Us and What To Do About It*. New York: Random House.

Barnbaum, D. (2011). You Get What Someone Else Will Pay For, *Theoretical & Applied Ethics* 1(2), pp 28-31.

Chang, P. L. (2006). Who's in the business of saving lives?, *Journal of Medicine and Philosophy* 31(5).

De George, R. T. (1994). International Business Ethics, *Business Ethics Quarterly* Vol. 4, No. 1, pp. 1-9.

O'Neill, O. (2002). *Autonomy and Trust in Bioethics*. Cambridge University Press.