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I. Introduction

Clinical research continually raises new regulatory and legal issues. One of the issues that has received attention more recently is whether subjects must be told of potential conflicts of interest by the investigator. This discussion has focused primarily on ethical considerations, e.g., the right of the potential subject to be aware of this information and the arguable impropriety of non-disclosure. While these aspects are undeniably important, there is an important independent factual issue: would potential subjects actually reach a different decision if they knew about the financial interests of the investigator? The purpose of this research project was to conduct an initial investigation of the impact of this knowledge on the willingness of subjects to participate in a study.

Pharmaceutical and device companies must overcome many hurdles in order to obtain approval from the Food and Drug Administration (FDA) and other regulatory bodies. For new drugs,[1] and for many devices, this typically necessitates, among other things, conducting one or more clinical studies. And that, in turn, requires identifying and recruiting subjects, and obtaining written informed consent from the subjects.

Informed consent forms serve multiple objectives. It is commonly stated that informed consent is a process, not a form. Yet while that is true, the consent form is generally the only documentation of what a potential subject has been told. In any subsequent dispute about the subject's state of knowledge, the consent form is likely to be the single most important piece of evidence. The form also provides a record to which subjects can refer after their oral discussions. FDA's regulations require consent forms to contain certain elements;[2] these elements convey the key information that subjects need in order to make an informed evaluation of whether to participate.

For example, potential subjects must be told, among other things, of the risks of participation, the benefits, the duration of their participation and alternatives. FDA's regulations also say that subjects must be apprised, if applicable, of certain other categories of relevant information, e.g., the number of subjects who will be participating and whether they will be told about developments that could affect their willingness to participate.[3]

However, another element, which is not enumerated in the regulation, has attracted considerable attention recently: whether a potential conflict of interest by the investigator needs to be disclosed.

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1 *See* 21 U.S.C. § 355(d) (defining "substantial evidence")
2 21 C.F.R. § 50.25(a)
3 21 C.F.R. § 50.25(b)

This issue first achieved prominence in the landmark case of *Moore v. Regents of the University of California*.[4] The lawsuit was filed after John Moore, who had had his spleen removed due to hairy cell leukemia, allegedly learned that his physician and some companies had used some of his cells to establish a cell line (the Mo cell line). Moore sued, claiming that he had a property right in his discarded cells. The California Supreme Court granted the defendants' motion to dismiss and rejected that claim, finding that Moore had no property right in the cells that had been removed.

This aspect of the decision is well known. A second line of attack by Moore, however, has received less notice but was viewed more favorably by the court. According to Moore, the principal investigator also was using Moore's biological material to develop the cell line without disclosing this role to Moore. In this capacity the investigator stood to benefit financially from Moore's continued participation in the study. The court declined to grant the defendant's motion to dismiss this claim. Instead, the court said, "[I]ndeed, the law already recognizes that a reasonable patient would want to know whether a physician has an economic interest that might affect the physician's professional judgement."[5] Since then, the issue of disclosure of conflicts of interest has become a more prominent topic, both within the clinical trial community and outside it.

For example, FDA has been criticized by Congress and others for having experts serve on its advisory panels who have conflicts;[6] the agency has announced that it is developing new guidance. Perhaps in response to this pressure, FDA issued approximately 30 percent fewer financial conflict waivers in 2006 than 2005.[7]

II. DISCLOSURE OF CONFLICTS

As a direct result of the concerns over conflicts of interest, the recently enacted Food and Drug Administration Amendments Act has multiple provisions relating to advisory committees and conflicts by members. This legislation, for example, limits the number of conflict waivers FDA may grant panel members, compels FDA to reduce the number of waivers each year, and requires advance public disclosure of these potential conflicts and their nature.[8] In a similar vein, many medical journals have tightened their policies on disclosure, and the reported failure of some authors to make disclosures has sparked controversy. Indeed, it is a rare week where there is not some new charge regarding conflicts or undisclosed conflicts, or a report involving conflicts of interest—alleged or real—in the medical field. Perhaps most poignantly, Dr. Lester Crawford, a former FDA Commissioner, pled guilty to two misdemeanor counts involving his undisclosed ownership of stock in companies subject to FDA regulation. One of these counts related to the failure to disclose a conflict of interest.

In the field of clinical research, FDA has determined that it wanted to have access to information regarding potential conflicts of interest by investigators. In 1998, the agency adopted a regulation requiring sponsors to disclose certain types

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[4] 793 P.2d 479 (Cal. 1990)

[5] Id. at 483.

[6] Robert Steinbrook, *Financial Conflicts of Interest and the Food and Drug Administration's Advisory Committees*, 353 N. ENG. J. MED. 116 (July 14, 2005).

[7] *FDA Issues Fewer Financial Conflict Waivers in 2006*, FDA WEEK, 13 at 11 (Mar. 9, 2007).

[8] Food and Drug Administration Amendments Act of 2007, Pub. L. No. 110-85, § 701.

of financial stakes by investigators, e.g., ownership of publicly traded stock worth more than $50,000 or any stock in a privately-held company.[9] FDA's disclosure regulations even require investigators to list financial arrangements between family members and the sponsor, e.g., ownership of stock by a spouse or minor child. Responding to the proposal, several commenters questioned what FDA would do with the information and "objected to the lack of objective criteria for use by FDA reviewers to evaluate financial interest disclosure statements."[10] The agency declined to provide any specific substantive response. Rather, FDA said "the specific financial arrangements and the steps taken to minimize bias…must be considered on a case-by-case basis."[11] FDA reaffirmed that it wanted the information, but did not say specifically what it would do with the data.

FDA's disclosure regulations, however, do not require that subjects in a clinical study be told about the potential conflicts of interest. FDA receives the information at the time of submission of the marketing application, but there is no FDA-based obligation for sponsors to notify the subjects.[12] Since the FDA financial disclosure rule has been adopted, it is not clear how, if at all, FDA has used this information in reviewing applications. (For example, in one recent case, FDA approved a new device even though all the data were based on implants performed by the surgeon-inventor, who according to the petition opposing approval, had a significant financial interest in the product.) FDA's recognition that it could not articulate even broad criteria for how it will use financial information when reviewing an application does suggest that providing clinical subjects with this information may raise a similar practical issue: how would subjects actually use this information in evaluating their options?

The issue of disclosure to subjects has arisen in other lawsuits since *Moore*. For example, one of the allegations in the suit brought after the death of Jesse Gelsinger in a gene therapy trial was related to the lack of disclosure of the investigators' financial stakes. The complaint alleged that the doctor conducting the research stood to make a profit from the research; the doctor had founded a company that had funded the research.[13] The case reportedly settled for over one million dollar payment to the plaintiffs.[14]

The issue of potential conflicts of interest is not limited to the extreme allegations found in *Moore* and *Gelsinger*. Most clinical investigators receive some compensation from the sponsor for serving as an investigator. This is typically on a per patient basis, but can also include incentives for rapid enrollment or reaching certain goals. Investigators may have other financial ties with the sponsor, such as receiving stock, serving as a consultant, membership on scientific advisory boards or acting as a paid speaker.

Thus, there has been considerable attention focused on issues relating to conflicts of interest, both generally and specifically, in the field of clinical research. A recent

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[9] 21 C.F.R. Part 54

[10] Financial Disclosure by Clinical Investigators, 63 Fed. Reg. 5233, 5236 (Feb. 2, 1998).

[11] *Id.*

[12] The requirement that FDA obtain more information than subjects is not unique to financial interests of investigators. Given the voluminous data received in Investigational New Drug applications, 21 C.F.R. Part 312, and most investigational device exemptions, 21 C.F.R. Part 812, it could not be otherwise.

[13] Gelsinger v. Trustees of the University of Pennsylvania, (C.P. Phila. Co., 2000) *available at* www.sskrplaw.com/links/healthcare2.html (last visited Oct. 5, 2007).

[14] *Id.*

study reported that "institutional academic-research" relationships (IAIRs) were "highly pervasive" in medical schools and large teaching hospitals.[15] The authors concluded, "Future research is needed to better understand the impact of IAIRs on the independent unbiased performance of the education and research missions of medical schools, the management and disclosure of these relationships at the institutional level and the impact of institutional policies."[16] These discussions have tended to focus on whether financial interest should be prohibited, or whether disclosure is necessary and/or sufficient. If the arrangement is prohibited, then empirical inquiry of how the conflict affects behavior of investigators or potential subjects is unnecessary. That is, if policy makers believe certain types of arrangements should be proscribed, the issue of what impact the conflict might have is rendered moot.

For example, Stanford University last year sharply curtailed gifts from pharmaceutical companies. In the policy issued by Stanford University it states that "[p]ersonal gifts from industry may not be accepted anywhere at the Stanford School of Medicine…. It is strongly advised that no form of personal gift from industry be accepted under any circumstances."[17] The American Association of Medical Colleges policy is more nuanced: "Institutional policies should establish the rebuttable presumption that an individual who holds a significant financial interest in research involving human subjects may not conduct such research."[18] The policy statement does permit the research to proceed if there are "compelling circumstances"; that determination is made on a case-by-case basis. A study of institutional policies at medical schools found that policies vary widely, and recommended that certain financial relationships be outright prohibited. Regardless of whether a ban is imposed for philosophical reasons, because of a concern that *any* financial stakes may improperly influence investigators' behavior, or for other reasons, the establishment of a ban obviates the need to research the true impact of the perceived conflict on researcher behavior or subject decision-making.

Imposing these types of bans, though, may be criticized as an overly mechanistic and narrowly focused approach to human behavior. There are many types of powerful influences that are unrelated to direct financial gain, e.g., pride, strong belief in a particular hypothesis, professional advancement or the quest for prestige. A former dean of a major medical school where there had been several research-related scandals recently stated at a conference for institutional review boards that not one of the several incidents at his school had their roots in money.

Moreover, bans are not always practical or may suffer from other significant drawbacks. They may also be perceived as paternalistic, depriving the other parties of the opportunity to evaluate the information regarding participation in the study with awareness of the potential conflict and then decide for themselves what

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[15] Eric Campbell, et al., Institutional Academic-Industry Relationahips, 298 J. Am. Med. Ass'n 1779 (Oct. 17, 2007).

[16] *Id.* at 1786.

[17] Stanford University, *Policy and Guidelines for Interactions between the Stanford University School of Medicine, the Stanford Hospital and Clinics, and Lucile Packard Children's Hospital with the Pharmaceutical, Biotech, Medical Device, and Hospital and Research Equipment and Supplies Industries ("Industry") available at* http://med.stanford.edu/coi/siip/documents/siip_policy_aug06.pdf.

[18] Association of American Medical Colleges, *Protecting Subjects, Preserving Trust, Promoting Progress—Policy and Guidelines for the Oversight of Individual Financial Interests in Human Subjects Research*. *See also* Eric Campbell et al., *Financial Relationships between Institutional Review Board Members and Industry*, 355 N. ENG. J. MED., 2321 (Nov. 30, 2006).

to do. In many cases, the preferred solutions to the researcher's financial ties will be disclosure, not prohibition.

This, in turn, raises the question of what impact this disclosure has on subjects' willingness to participate. Put simply, to what extent do subjects consider a potential conflict in deciding whether to participate? A study published last year in the *New England Journal of Medicine* concluded that the willingness of cancer patients to participate in research would not be affected by the financial ties of the physician.[19] When asked questions about the impact of knowing that the investigator stood to benefit financially from the trial, most patients said that they would still participate despite the financial stake.

One limitation in this important study was that there was no control group. Another possible limitation, the authors of that article stated, was that the seriousness of the patients' condition may have caused them to give less weight to the potential financial stake of the investigator.

III. THE STUDY

Given the importance of better understanding the decision-making process, we conducted an initial study into the question of what impact an investigator's financial stake has on subjects' willingness to participate in a study. By using a fictitious study, we were able to create and compare the role played by different experimental conditions. The research used a study scenario where participation was entirely discretionary. This eliminated the pressure that could arise in a scenario involving a life-threatening illness where the subjects might have believed they had little choice but to participate.

A. *Methodology*

The present investigation was designed to investigate the effect of level of risk, level of compensation and conflict of interest on willingness to participate in a fictitious research project. The sampling frame for the project included students enrolled in anthropology and sociology courses at George Mason University (GMU) in Fairfax, Virginia. Courses were chosen that satisfy the University's general education requirement, thus ensuring a broad cross-section of GMU students.

Data were collected by self-administered questionnaire from 297 undergraduate students between April 13 and April 18, 2006. The survey instrument contained 14 questions. The study received approval from the GMU Human Subjects Research Board on March 6, 2006. The sample used in this analysis was 65 percent female, had a mean age of 22 years and a mean grade point average (GPA) of 3.18.

The research focused on subjects' willingness to enroll in a fictitious research study that would assess the effectiveness of a dietary supplement to see whether it could improve memory. Each of the research participants received one of 18 different versions of an informed consent document designed to vary three main independent variables in the study: 1) level of risk, 2) level of conflict of interest, and 3) level of compensation. The primary dependent variable in the study asked the subjects to rate, on a scale of 1 to 7 (with 7 meaning most willing), their will-

[19] Lindsay Hampson et al., *Patients' View on Financial Conflicts of Interest in Cancer Research Trials*, 355 N. ENG. J. MED., 2330 (Nov. 30, 2006).

ingness to participate in this fictitious study. The mean for the distribution of this variable was 3.83 with a standard deviation of 1.91.

Level of *conflict of interest* presented three variations. In one scenario, subjects were told that the principal investigator for the study was a faculty researcher and an employee of the company that developed the dietary supplement. In a second scenario, presented to other subjects, they were told that the principal investigator was a faculty researcher, was an employee of the company that developed the dietary supplement, and would receive a payment for each individual who completes the study. The third scenario presented the highest level of conflict of interest and informed the subject that the principal investigator was a faculty researcher, had helped develop the product and, as a co-owner of the patent for the product, would receive royalty payments from all potential sales of the product.

The second independent variable was the level of *risk*. Again, there were three levels. The low risk scenario informed subjects that there were "no known side effects from any of the individual ingredients in the product," the moderate risk scenario informed subjects that "one of the ingredients on rare occasions causes mild headaches, and another has reportedly caused short-term dizziness in a few individuals," and the higher risk scenario informed subjects that "two of the ingredients occasionally cause headaches, and another has reportedly caused nausea and diarrhea in some individuals."

This variable permitted an assessment of the interaction between the level of risk and the strength of the potential conflict. For example, if the perceived conflict of interest is high but the expected risks negligible, it may be that the potential subject simply would be less concerned about the conflict of interest. In essence, a subject could choose to ignore even an investigator's potentially powerful financial interest in the belief that it did not affect the subject's own interests because of the absence of expected harm. Conversely, the level of concern raised by an investigator's greater financial stake may be higher if the risks of the participation are higher, particularly since no significant benefits were described in the scenario.

The third independent variable assessed the influence of *compensation* on the participation decision. In one scenario the respondents were informed that they would receive $20 for participating, while a second scenario informed participants that there would be no compensation offered.

Thus, the research had a total of 18 scenarios: 3 levels of conflict by 3 levels of risk by 2 levels of compensation. Table 1 presents the distributions for these variables. Each subject was asked to read the informed consent document containing one of the eighteen scenarios and then complete the 14 item questionnaire.

In addition to these main independent variables, four other independent variables were assessed for their effect on willingness to participate in the fictitious research project: perceived benefit of the product, perceived trust of the principal investigator, perceived safety of the product, and perceived need for more information about the product. *Perceived benefit* was assessed by asking the following question: "How much benefit might this new product offer you personally?" *Perceived trust* was assessed by asking the subject: "How likely do you think it is that the research investigator will supply good quality information about the study?" *Perceived safety* was assessed by asking, "How concerned are you about the overall safety of the product?" *Perceived need for information* asked, "Is there any other information that you would like to receive about the study before deciding to participate?" Perceived benefit, trust and safety were each measured using a seven-point scale with higher

values indicating higher levels of intensity on the variable under investigation, e.g., greater perceived benefit. The distributions for perception of benefit, trust and safety had means (standard deviations) of 3.83 (1.95), 4.85 (1.66) and 4.68 (1.79), respectively. Perceived need for more information about the product was asked in a yes or no format with 69.38 percent of subjects answering "Yes."

Table 1: Distribution of subjects by Risk, Conflict and Compensation Variables

	Frequency	Percent
Risk		
Low	101	34.01
Medium	98	33.00
High	98	33.00
Conflict of Interest		
Low	102	34.34
Medium	95	31.99
High	100	33.67
Compensation		
No	147	49.49
Yes	150	50.51

B. *Results*

Multiple regression analysis was employed to investigate the effect of each of the main independent variables on willingness to participate in a fictitious research project while controlling for the other variables in the model. Table 2 presents the results from these analyses. In all, neither level of *risk* nor *conflict of interest* exhibited a significant relationship with willingness to participate in the fictitious research project. Potential subjects were as likely to participate when there were no known side effects or the side effects were more substantial. Similarly, they were as likely to be willing to participate when the investigator was a patent holder or simply an employee of the company. In contrast, level of compensation had a significant effect on willingness to participate ($t = 2.22$, $p = 0.028$). Subjects who were offered compensation were significantly more likely to participate in the fictitious research project.

While the potential for conflict of interest appeared to play no role in subjects' decision to participate in the study, the more general perception of trust in the research investigator exhibited a significant positive relationship with willingness to participate. Subjects who trusted the investigator to present quality information about the study were significantly more likely to participate in the study ($t = 5.55$, $p = .000$). Likewise, subjects who felt that the dietary supplement would offer them a personal benefit were more likely to participate in the study ($t = 6.95$, $p = .000$). In contrast, significant negative relationships were uncovered for the regression of willingness to participate on the *perceived need for more information* ($t = - 2.35$, $p = .020$) and *perceived safety* of the product ($t = - 2.49$, $p = .013$). That is, subjects who believed that they needed more information or were concerned about

the safety of the product were significantly less likely to participate. The perceived safety by subjects was not related to the risk levels established in the three scenarios. Thus, the perception of risk was not significantly different for when subjects who were told there were no known side effects compared to subjects who were told of the possibility of headaches, nausea and diarrhea.

Table 2: Unstandardized Regression Coefficients and Standard Errors for the Regression of Willingness to Participate

	Regression Coefficient	Standard Error
Risk	.07	.12
Conflict	.20	.11
Compensation	.42*	.19
Perceived benefit	.37***	.05
Perceived trust	.37***	.07
Perceived need more info	-.49*	.21
Perceived safety	-.14*	.06
GPA	-.10	.19
Age	-.03	.02
Sex	.09	.21
Intercept	2.28*	.98

R^2 for the model	= .425
Adjusted R^2	= .400

*	= p < .05
**	= P < .01
***	= p < .001

One of the objectives was to generate a scenario where the likelihood of benefit was perceived differently by subjects. If the proposed product was uniformly viewed as highly beneficial or very unlikely to provide a benefit, then the independent variables would be less likely to have an effect. The distribution did show substantial variability, with roughly equal number of subjects believing it would be useful (38 percent) and not useful (41 percent). Despite this discrepant perception among subjects of benefit, the actual description of benefit was identical in all of the scenarios.

None of the demographic variables (i.e., GPA, age, sex) was significant in the multiple variable model. It should be noted that bivariate correlations indicated that younger students and those with lower GPAs were more willing to participate in the study. However, the loss of significance in the multiple variable model indicates that the effect of each of these demographic variables on willingness to participate is transmitted (mediated) through the effects of the other significant independent variables (e.g., perceived safety) discussed above. There were no significant bivariate correlation between gender and willingness to participate.

IV. DISCUSSION

There has been a significant trend towards curbing participation in clinical studies by investigators who may have a financial interest in the outcome or relationship with the sponsor. This trend is based on a belief, which appears to have some empirical support,[20] that this financial interest can affect the behavior of investigators. Whether this is actually the case and to what extent and under what circumstances is outside the scope of this study. However, restrictions on investigator participation do have consequences for the clinical investigation process. For example, a prohibition on the participation of *any* investigator with *any* financial arrangement with sponsors would have far-reaching effects on the available pool of qualified investigators, and may have an impact on the opportunity of some potential subjects to participating in a study.

A second issue relates to whether subjects *ought* to be told of financial interests. There is certainly an important ethical component to that issue. Disclosure is widely viewed by lawmakers as good policy, as evidenced by the new provisions relating to FDA advisory members and state laws mandating disclosure of gifts to doctors.[21] But there is also another side to the coin: would this knowledge make a difference?

The findings from this pilot study suggest that by and large it would not. Subjects were roughly as likely to say they would participate when told the investigator had no financial relationship as when told the investigator held a patent. The recently published study by Hampson, et al of cancer patients is similar. The majority of patients said they would still participate even if they knew their physician had a potential financial stake.

In the study of cancer patients, the lack of impact may be attributable to the severity of the patients' needs playing a much larger role in the decision-making process than concerns about a potential conflict. In this study, it could be the converse—the study was viewed as being of relatively trivial overall importance and of relatively low risk, and therefore the investigator's financial interest was of relatively low importance in the evaluation process.

This study did attempt to evaluate this factor by creating three levels of risk. Changing the level of risk did not significantly affect willingness to participate. Nor was there a significant interaction between the risk and financial stake variables. It may be that the effects of the combined risk-stake variables would have been more pronounced if the risks had been greater.

The likelihood study subjects would participate was influenced by modifying only one study parameter. Offering a $20 payment significantly increased the likelihood of participation ($p < .05$). While this may seem to be a nominal amount, it clearly affected decision-making in the undergraduate students who participated in the study. However, subjects were about as likely to participate if the investigator held a patent as when the investigator stood to gain nothing personally. And the likely rate of participation was the same for no side effects versus when the ingredients were associated with headaches, nausea and diarrhea.

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[20] *Study: Conflict of Interest Common in Orthopaedic Product Studies*, Devices & Diagnostics Letter Online; Justin Bekelman et al., *Scope and Impact of Financial Conflicts of Interest in Biomedical Research*, 289 J. AM. MED. ASS'N, 454 (Jan. 22, 2003); Lisa Bero et al., *Factors Associated with Findings of Published Trials of Drug-Drug Comparisons: Why Some Statins Appear More Efficacious than Others*, 4 PLOS MED., June 2007, at 1001. These conclusions have been questioned.

[21] *See* Minn. Stat. § 151.461

Perceived trust of the investigator was significantly related to willingness to participate. The perception of trust, however, was not correlated with the level of financial stake or the other two variables. It is not clear whether subjects were more willing to participate because—on whatever basis—they had concluded that the investigator was trustworthy, or they first decided that they wished to participate and that influenced the way they responded to the question regarding trustworthiness, or due to some other mechanism. The basis for the means by which they formed trustworthiness evaluations is an area meriting further research.[22]

Regardless of the means by which trustworthiness was assessed by the students, it does not appear to have been affected by information regarding the investigator's financial interests, or any other variable. Because the subjects were undergraduate students, they may have been less appreciative of the possible effects of patent ownership on behavior. (Of course, the same lack of understanding could be true for many other, less financially savvy would-be participants.) An alternative hypothesis would be that many students were cynical about the investigator's motives, irrespective of the nature of the investigator's financial stake. That is, they may have perceived only a negligible difference in the level of self-interest between being an employee of the sponsor versus being an employee *plus* being a patent holder.

Understanding better the actual impact of conflicts on decision-making has real world significance. This point is illustrated by a recent lawsuit against CVS Pharmacy.[23] CVS had entered into a program with Merck & Co. Inc. which involved sending letters to customers who had received prescriptions for specified drugs. CVS earned approximately one dollar per patient. The plaintiff alleged that CVS' mailing information to customers and not disclosing that it stood to earn a dollar was actionable under Massachusetts laws.

The court agreed with the plaintiff:

> When a pharmacy provides medical advice to its patients, but fails to reveal to the patient that the pharmacy is making a net profit each time it provides that medical advice, it is depriving its patient of critical information that the patient needs in order reasonably to evaluate that advice. Without such information, the patient, in view of the pharmacist's duty of care, reasonably may assume that the advice was provided solely out of concern for the health and best interests of the patient. With such information, the patient reasonably may question whether the advice was intended to serve the health and best interest of the patient or the financial health and best interest of the pharmacy.[24]

Thus, the court assumed that learning of the $1 payment was "critical information" that a patient needed. The empirical research in this study suggests, however, that the court's assumption may have been incorrect. As courts confront other instances of undisclosed payments, it would be helpful to be able to base decisions on empirical evidence, not assumptions.

This pilot study has several major limitations in extrapolating to clinical research. The research scenario was relatively benign, simple and low risk. The subjects were

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[22] *See* Edward Gabriele, "Shifting the emphasis, protection follows from trustworthiness," *Protecting Human Subjects*, (No. 12 Summer 2005) at 19.

[23] Kelley v. CVS Pharmacy, Inc., No. 98-0897, 2007 Mass. Super. Lexis 381 (Mass. Sup. Ct. Aug. 22, 2007).

[24] *Id.* At *24.

all students at a single campus, and 90 percent were 25 or younger, hence heterogeneity was limited. Subjects were asked their willingness to participate in a planned study, not to give actual consent. It is not clear why so many subjects were willing to participate, and so many others were not, on the same set of facts. There are certainly many factors that determine willingness to participate, and knowledge of an investigator's financial stake is only one piece of data that subjects must consider. Thus, further research is needed on this topic.

V. CONCLUSION

Whatever the reasons for the different responses, the likelihood of participation was not shown to be affected by the investigator's financial stake. The results from this study do indicate that other factors played a much more significant role in these subjects' interest in participation than the nature of the investigator's financial interests. This does suggest that policymakers should not reflexively impose politically attractive but onerous disclosure requirements, particularly when those requirements will likely have adverse consequences, e.g., limiting the pool of investigators or creating costly systems to manage the information. Disclosure requirements perhaps may be grounded on ethical grounds or on the basis of an interested party's right to know, regardless of empirical research into decision-making. However, the utility of mandating disclosures may be questioned if, as was the case in this pilot study, the disclosures do not affect the decisions of the individuals who receive the information.