On Gnats, Camels and Payment to Research Subjects: A Commentary

Robert A. Burt
Yale Law School

Follow this and additional works at: http://digitalcommons.law.yale.edu/fss_papers
Part of the Law Commons

Recommended Citation

This Article is brought to you for free and open access by the Yale Law School Faculty Scholarship at Yale Law School Legal Scholarship Repository. It has been accepted for inclusion in Faculty Scholarship Series by an authorized administrator of Yale Law School Legal Scholarship Repository. For more information, please contact julian.aiken@yale.edu.
ON GNATS, CAMELSS, AND PAYMENT TO RESEARCH SUBJECTS: A COMMENT

By Robert A. Burt

Lainie Friedman Ross refreshingly challenges the accepted wisdom that there is some intrinsic wrong in compensating adult subjects for participating in non-therapeutic research and something even worse about compensating children (or, by implication, other incompetent subjects) whose participation depends on surrogate consent. Notwithstanding the clarity of her reasoning and the underlying boldness of her essay, however, something stopped Dr. Ross short of advocating complete revision of the conventional prohibitions. “The offer of money” she says, “becomes morally objectionable if it gives ... an incentive to take a risk that one would not otherwise take.”

Opponents of any compensation might readily argue that this formulation is too sponge-like to give any guidance for distinguishing between objectionable and unobjectionable compensation—except perhaps to permit compensation for out-of-pocket expenses, such as travel costs. But that is not my concern with Dr. Ross’s formulation. My concern—my puzzlement, to be more precise—is in identifying exactly what is wrong with payment that provides an incentive to accept risks that would otherwise not be taken.

My puzzlement starts from recognition that our society does not consistently condemn the use of monetary incentives to induce socially valued conduct, even when that conduct involves considerable risk to personal health. If proof is required for this proposition, we need only look to recent accounts about “imminent danger pay” supplements for military service in Iraq and huge bonuses to private sector employees who are willing to drive trucks or oversee oil rigs in reconstruction efforts there.¹ If we acknowledge that participation in biomedical research can yield social benefits at least as substantial as service in Iraq, why then do we unquestioningly offer monetary incentives to induce risk-taking in one setting but not the other? Dr. Ross’s reasoning suggests that the “voluntary character” of participants’ consent is more questionable in deciding to participate in biomedical research as compared to deciding whether to participate in the reconstruction of Iraq. But I am not entirely convinced by this distinction.

There is indeed an important difference between the two contexts. Biomedical research is conducted by physicians or other scientists who are publicly viewed as part of the health care profession. The mantle of this profession—the “white coat” of the physician or experimenter—conveys a very different popular understanding

¹ Alexander M. Bickel Professor of Law, Yale University.

from army uniforms or government bureaucrats' grey flannel suits. The public understanding that frames encounters with health care professionals is that they are healers—and this understanding is so potent (because it conforms to such powerful wishes to be cared for in sickness) that the lay public is likely to disbelieve or entirely disregard even the most insistent warning from a health professional that participation in biomedical research or treatment carries any risk of personal harm or, indeed, that participation is unlikely to provide any personal benefit. (Thus the repeated empirical observations that participants in avowedly non-therapeutic protocols, especially participants who are afflicted with some illness, routinely believe that some benefit is possible for them, regardless of the researchers' clear insistence to the contrary.2)

This public trust in the healing potential (that is, the risk-free character) of any interactions with health care professionals has been sorely and visibly challenged in recent decades—with steep declines in trust among specific minority groups but even marked reductions among the general public.3 This increased skepticism might appear to be a sufficient counterweight to the older attitudes of unquestioning faith, and might promote the likelihood that potential research subjects are as equipped to make voluntary decisions about entering research protocols as they are in deciding whether to go to Iraq. I believe, however, that the wish for protection against illness remains so strong among the lay public that they are likely to disregard not simply specific warnings about research risks but their own repeated observations about the unreliability of the health care profession. In a word, the lay public is ambivalent in their assessment of the trustworthiness of the profession—worshipful and scornful at the same time; and this ambivalence is as likely to cloud realistic judgments in deciding to enter research protocols as in any dealings with the health care profession.

But even if this is so, what direct relevance does it have for deciding whether to provide monetary incentives for research participation? Is there adequate reason to think that public credulity about the risks of research will be increased by monetary incentives—or is it more likely, as I am inclined to believe, that the promise of money adds very little to whatever inclination already exists among the lay public to believe only the best about the possible outcomes of their encounters with health care professionals?

Indeed, the explicit offer of money in exchange for participation seems at least as likely, and perhaps even more likely, to alert the potential research subject to possible risks than to disguise those risks. Potential subjects asked to participate based solely on their altruism seem likely to assume that their good motives in

2. See sources cited in Ross article at note 49.
themselves will protect them from harm. (There is an old joke that no good deed goes unpunished; but the joke would not be funny if we truly believed in its truth.) Put another way, it seems more likely that an uncompensated research subject would disbelieve the possibility of harm more than a potential subject who consciously realizes that he must be induced to participate by some tangible payment. If voluntary understanding of the risks of the research enterprise is our goal, then we should emphasize visible similarities to “imminent danger pay” offered to soldiers and civilians in Iraq rather than insisting on the dissimilarities. Thus I would conclude that, whatever the merits of Dr. Ross’s stricture that payments are “morally objectionable” if they provide incentives to take risks not otherwise acceptable, this is not because the payment incentive significantly undermines research subjects’ “voluntariness” in deciding whether to participate.

A different and stronger basis for Dr. Ross’s stricture might arise from the special circumstances of children as research subjects. Payments in an amount sufficient to provide incentives for participation are likely, as Dr. Ross suggests, to create conflicts between the welfare interests of children and the financial interests of their parents. I believe, however, that there are other ways to address this problem and that these alternatives are preferable where parents are reluctant to consent to their children’s research participation and there is an important social need to obtain such participation. I would expect (and hope) that parents are much more reluctant to consent to their child’s participation in nontherapeutic than in therapeutic research. I would expect (and hope) that parents would subject their child to any risk as a research participant only if some therapeutic benefit might thereby accrue to the child.

Research subjects may be willing to accept some risk of personal harm in nontherapeutic research for entirely unselfish motives of benefitting society. But I am not persuaded that subjecting one’s children to such risk, even for identically unselfish motives, is an appropriate exercise of parental authority. Parents may indeed want, as Dr. Ross observes, to inculcate an ethos of selfless social service in their children; but the proper means for such inculcation is for the parents to embody this ethos in their own conduct, not to conscript their children into the enterprise before they are capable of making this choice for themselves. As the Supreme Court famously observed, “Parents may be free to make martyrs of themselves. But it does not follow that they are free in identical circumstances to make martyrs of their children.”

This concern is not met by a rule that parents may consent to their children’s participation in nontherapeutic research so long as the parents’ motive is unaffected by any prospect of financial gain. This concern can only be met by a rule that children cannot be subjected to any risk of personal harm in nontherapeutic

---

research. Current regulations permit "minimal" risk in such research. Some remote possibility of some small harm can always be imagined in any endeavor, and I would construe the current regulatory regime accepting "minimal" risk for children in nontherapeutic research in this spirit. If the regulators follow this path in calibrating acceptable risk for such research—accepting only highly unlikely possibilities of extremely small harmful outcomes—then it would not be necessary to impose further limits on parents' motives to protect their children against self-dealing by their parents. Whether the parents consent to their children's participation from "pure" motives of high altruism or from "impure" motives of financial gain, the crucial point is that the children would not suffer any plausible prospect of harm from the research.

Put another way, we should not rely on parents to protect their children from any risk of harm in nontherapeutic research. We should rely on systematic regulatory oversight of the research enterprise for such protection. We should design institutional regulations to ensure that no parent is ever asked (or permitted) to agree that his or her child may participate in nontherapeutic research involving any plausible risk of harm.

The existence of such a regulatory regime is not in itself an argument for providing financial incentives for parents to consent to this research. But with the existence of such a regulatory regime, there no longer is a good reason to insist, as Dr. Ross does, that payments are morally permissible only if they do not provide incentives for children's participation. If there is an important social benefit to be obtained from children's participation and it is otherwise difficult to recruit sufficient numbers of children to realize this benefit, then a financial incentive for participation would be justified—but only because the children's interests could not plausibly be harmed as a result of their participation.

5. See sources cited in Ross article at note 44. Under the Federal Regulations risk is "minimal" if "the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests." Sec. 46.102i.

6. The Federal Regulations do permit "a minor increase over minimal risk" for nontherapeutic research with children suffering from an illness if the research presents "a reasonable opportunity to further the understanding, prevention, or alleviation" of this illness in the future for other children. Sec. 46.406. This is an infliction of possible harm to some children, in ways that have no prospect of benefitting them, in order to benefit other children—an explicitly admitted violation of the Kantian imperative against using human beings as means rather than as ends in themselves. In an earlier article, Dr. Ross correctly criticized this provision: "[E]xposing children with a disorder or condition to greater risk . . . place[s] further burdens on already burdened persons . . . and is unjust." Lainie Friedman Ross, Do Healthy Children Deserve Greater Protection in Medical Research? J. PEDIATRICS 108, 110 (February 2003).

7. The calculus for children's participation in therapeutic research would be different. The child's illness and the prospect of personal therapeutic benefit would justify a larger quantum of risk-taking. These factors would also provide a strong motive for parents to consent to their children's participation. Financial payments for participation would increase this motive, but unlike the
It may be, however, that the demanding regulatory regime that I envision would never be reliably followed in practice, even if the regulators consistently avowed that they were applying the most stringently imaginable child-protective standards. It may be that research regulators—the members of local institutional review boards as well as officials in national oversight agencies—so powerfully see themselves as professionally allied, even implicitly as co-venturers, with medical researchers that they are too much inclined to minimize risk to human subjects in the service of their shared goal of scientific progress. The impediments to carefully balanced assessments of risks and benefits that concern Dr. Ross afflict researchers and research regulators at least as powerfully as they affect potential research subjects and the parents of potential subjects.

The vulnerability of research scientists and their professional regulators to these impediments, however, raises a moral issue in ways that are not relevant to the vulnerability of lay participants in research. Research scientists are morally obliged to protect research subjects. Research subjects are entitled, but not necessarily morally obliged, to protect themselves; and their exercise of this right to self-protection depends on the honesty and good faith of the professionals engaged in the research science enterprise. Parents are morally obliged to protect their children in ways similar to the general protective obligation of research scientists; but parents are dependent on the honesty and good faith of the professionals in discharging their own moral responsibility to their children. Accordingly, the suspicion that research regulators routinely fail to meet their protective obligations undermines the moral integrity of the research enterprise much more insidiously than the possibility that some research subjects or parents of subjects might be motivated more by financial gain rather than by altruism. This is true even if the regulators are deceiving themselves about their own good faith; indeed, the likelihood of this moral self-deception increases the difficulty of effectively combating the immoral practices.

From this perspective, it is understandable that research scientists, both at the bench and in regulatory chairs, would be intensely concerned with assuring the moral integrity as well as the appearance of integrity of the research enterprise. From this perspective, we can better understand the elaborate insistence, currently on display in various professional fora, that researchers must be entirely free from any financial conflicts of interest and entirely “pure” in eschewing such base motives. These protestations of purity are, of course, difficult to reconcile with the realities of self-interested gain sought by researchers in academic promotion, in the pursuit of regulatory regime that should govern nontherapeutic research, these increased motives could lead parents to discount real risks of harm to their children. A genuine conflict of interest between parents and children would thus arise. For this reason, provision of financial payments for children’s participation in therapeutic research is difficult to justify.

of reputation and prizes, and the prospect of lucrative commercial arrangements that will predictably follow (for researchers and their University employers) from success in the research endeavors of "pure science." The visible discrepancy between protestations of moral purity and the realities of crass commercialism has only served to redouble the purifying efforts of the publicly visible avatars of the research enterprise.

The moral doubts clustering around the entire research enterprise—whether it is nobly altruistic or basely self-seeking—appear to me to serve as a background impetus supporting the current conventional rule against permitting any financial compensation for subjects in therapeutic or nontherapeutic research. Dr. Ross has convincingly shown the illogicality of this rule. But her condemnation on avowedly moral grounds of any financial gain that might actually motivate a research subject's participation—her reluctance to follow the logic of her underlying argument—seems to me to arise from the same background impetus.

Her gesture toward preserving the appearance of moral purity in the research enterprise may be justifiable. But in this understandable caution, Dr. Ross may be unnecessarily turning away from realizing the social benefits that could come from payments sufficient to motivate participation in scientific research. Preserving the moral integrity of the research enterprise is a vitally important pursuit. But financial compensation to research subjects is not a prime suspect in the search for the agents responsible for wrongs that must be undone. Forbidding compensation to research subjects or limiting it in ways proposed by Dr. Ross focuses attention on the wrong target in combating the harmful distortions of self-interest in the research enterprise. To borrow the language of high moral authority, this focus is "straining out a gnat and swallowing a camel." Paradoxically enough, rigid constraints against financially self-interested motives for subjects' participation in research may harm the research enterprise without providing any commensurate protective benefit.