

## **Risk, Double Effect, and the Social Benefit Requirement**

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### **ABSTRACT**

Many ethicists maintain that medical research on human subjects that presents no prospect of direct medical benefit must have a prospect of social benefit to be ethical. Payment is not the sort of benefit that justifies exposing subjects to risk. Alan Wertheimer has raised a serious challenge to this view, pointing out that in industry, social value is not considered necessary to make dangerous jobs ethical. This article argues that Wertheimer was correct to think that the ethics of hazard pay should be the same in medical research and in business. Nevertheless, a qualified social benefit requirement should apply in both fields. For a study or a job with significant net physical risk to be ethical, it must have social value beyond the satisfaction of ordinary preferences, including the preference for money.

The requirement derives from a non-absolutist version of the doctrine of double effect. If a risky study or a dangerous job has no distinctive social value, and hazard pay is subjects' or workers' only reason to undergo risks, the very fact that they undergo risk is intended as a means to a financial end. Inviting people to enroll in such a study or to take such a job wrongfully treats people as mere means. By contrast, if a study or a job has social value, people can participate with a primary end other than money, even if they accept compensation. Researchers or employers do not intend but merely foresee risks to subjects or workers.

## INTRODUCTION

In medical research, it is common to pay research subjects for their participation, especially in studies which offer no prospect of medical benefit to participants, such as safety studies of new drugs and tests of new imaging technology on healthy volunteers. There is controversy about how much compensation is appropriate. Some have argued that subjects should be compensated only for their time and for the direct financial costs of participation (e.g. parking fees), not for the risks they undergo.[1,2,3] Others argue that there is nothing wrong with compensating subjects financially for the risks they undergo.[4] Until recently, medical ethicists generally agreed that paying subjects to participate in medical research cannot *justify* exposing subjects to physical risk. For the risks of research to be ethical, there must also be either a prospect of social benefit from research or a prospect of direct medical benefit to subjects.[3, 5, 6] If research that imposes health risks on subjects has no prospect of medical benefit to subjects, it must have a prospect of social benefit, typically involving improvement to health care, to be ethical. Payment is not a benefit that could help justify exposing healthy volunteers to health risks, such as the cancer risk associated with receiving a CT scan or the complex risks of being among the first people to ingest a new drug. Thus, for example, it was unethical for chemical companies in the 1990s to pay healthy volunteers to ingest a pesticide in the hope of persuading the FDA to relax regulations on pesticide residues in food.[7] It would likewise be unethical to recruit healthy volunteers for a first-in-human trial of a “me too” drug that is expected to have serious side effects and that is not expected to improve medical practice

in any way because several other drugs with similar efficacy and side effect profiles are already approved.<sup>1</sup>

Recently, the social benefit requirement in medical research has been challenged. Wertheimer argues that in many contexts, people quite reasonably regard benefits unrelated to health as adequate compensation for taking a health risk.[8] The value of seeing a relative can justify loading one's family into a car and undergoing the physical risks of being on the road. Many jobs involve physical danger. Though some dangerous occupations involve protecting people's health and safety, some arguably have no social value other than satisfying people's tastes and preferences. Wertheimer specifically identifies lobster fishing as a dangerous job that is "not a high social value occupation." He argues that whether people in dangerous occupations are wrongfully exploited depends in part on how much they are paid. This implies that people in dangerous occupations with low social value are not exploited if they are paid well enough. If payment is a benefit that justifies exposing lobster fishermen to risk (with their consent), it is also a benefit that can justify exposing medical research subjects to risk (with their consent). Waste of resources is also a salient ethical issue, but it is less salient, Wertheimer argues, when research is privately funded.

This article accepts Wertheimer's major premise while challenging his conclusion. The correct ethical standards for paying people to take health risks are indeed the same in medical research and in other contexts, such as employment. But there is an under-appreciated ethical requirement in business that parallels the social benefit requirement: dangerous jobs can be justified only by goods other than payment, most commonly the work's social necessity or some

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<sup>1</sup> If there are several drugs already on the market, or if prices are regulated, there may be no reason to expect that increased competition will enable more people to afford medicine.

other distinctive form of social value.[9] Mere satisfaction of ordinary economic preferences is not the sort of value that can justify workplace hazards. More generally, it is unethical to invite someone to engage in a risky activity if hazard pay is the *only* plausible reason for that person to engage in the activity. If hazard pay is the only reason to take a serious physical risk, then the very fact that this person is exposed to risk is a means to a financial end. Intending a serious risk as a means to an end violates the doctrine of double effect. Thus, payment and informed consent are not jointly sufficient to make it ethical to expose someone to a serious health risk. In a research context, only the prospect of direct medical benefit to subjects or the prospect of a socially beneficial advance can justify exposing subjects to serious health risks. This social benefit requirement applies equally to publicly funded and privately funded studies.<sup>2</sup>

## **1. THE ALLEGED ASYMMETRY BETWEEN MEDICAL RESEARCH AND EMPLOYMENT**

Is there a good reason to think that social benefit (other than payment or profit) is required to make net-risk research on healthy volunteers ethical, but that no such social benefit requirement should apply to hiring people for hazardous jobs? The justification for treating research risks and occupational risks differently cannot be simply that medical researchers have role-related obligations that businesspeople lack. If researchers have different role-related obligations from businesspeople, we need an explanation why the obligations of these social roles ought to differ as they do. The justification for the divergence in views cannot be that the risks of participating in research are larger than the risks of dangerous occupations. Some jobs, such as fishing and logging, are very dangerous indeed. In the United States in 2017, there were

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<sup>2</sup> It is thus more demanding than the qualified social benefit requirement Resnick defends.[10]

99.8 fishing fatalities and 84.3 logging fatalities per 100,000 full-time equivalent workers.[11]

Nor can the justification be that the risks of research participation are more difficult to understand or more difficult to appreciate. The risks of chemical exposure in an industrial context may be just as complex as the risks of ingesting an experimental drug.

Arguably, research subjects are typically more passive than workers, including “unskilled” workers,[12] but it is unclear why this fact would support a sharp ethical distinction between work and research participation. Some forms of work involve no activity other than mechanical compliance with instructions. Compliance with instructions is an important aspect of research participation, especially in some risky forms of research such as challenge studies. Moreover, workers may not have any more agency over the risks of work than subjects have over the risks of research. (Again, consider workplace chemical exposure.) Concerns about the passivity of research subjects arguably justifies treating them *more* like workers, providing protections like those of the workplace.[13]

Wendler and Rid suggest a salient difference between net-risk research with no social value and hazardous jobs with no social value.[6] Employing people in hazardous jobs whose product has no social value may be justified if taking the job is the only way for the employees to meet their basic needs. Working in a dangerous factory making fancy dresses would be an example of such a job, Wendler and Rid suggest. Clinical research differs in that the associated payment generally does not enable subjects to meet their and their dependents’ basic needs, since research participation is usually short-term and infrequent. Wendler and Rid’s distinction explains why there could be an ethical difference between hazard pay in research and hazard pay for dangerous jobs taken out of desperation. But many people employed in jobs that involve health risks did not

take those jobs out of desperation; they could have found other ways, e.g. physically safer jobs, to meet their and their dependents' basic needs. So Wendler and Rid's distinction does not support a social benefit requirement that applies only to research. Indeed, they would apply a social benefit requirement also to hazardous jobs not taken out of desperation.

There is a contingent reason for regulators to impose a social benefit requirement on clinical research but not on employment.[6, 8, 14] For clinical research to flourish, it must have public support. If loss of public trust leads to a reduction in public funding, in the supply of willing research subjects, or in potential scientists' enthusiasm for research careers, research will languish. Enforcing a social benefit requirement may help to secure public trust in the research enterprise. Of course, public trust is relevant to the flourishing of business, too. But perhaps people tend to regard the death of a paid volunteer in medical research as more scandalous than the death of a worker on a lobster fishing boat. Though this concern about public trust may justify *regulations* that impose a social benefit requirement on human subjects research but not on employment, it cannot by itself support an *ethical* requirement with this limitation. To defend an ethical social benefit requirement that is limited to research, as opposed to a regulation, one would need to explain why people should think the death of a healthy research volunteer more scandalous than the death of a healthy fisherman.

If there is no principled reason to distinguish health risks in medical research from health risks in employment, we face a choice. Should we conclude that hazardous research and hazardous jobs can be ethical even if they have no social value other than financial benefit? Or should we conclude that both in medical research and in business, inviting people to take health

risks is acceptable only if the activity has a social benefit other than a financial benefit to the participants?

## **2. RISK AND DOUBLE EFFECT**

A social benefit requirement, both for paid work and for paid research participation, can be grounded on the doctrine of double effect, which in turn can be grounded on various moral principles, among them the Kantian formula of humanity. The doctrine of double effect has been formulated in various ways.[15] This paper uses a non-absolutist form of the doctrine. If the reasoning that motivates an action involves intending harm either as an end or as a means to an end, then the agent acts unethically unless the action has a special justification (e.g. that it will prevent a truly grave evil). If the only plausible reasons for performing a certain action involve intending harm either as an end or as a means to an end, and no special justification is available, then the action is impermissible. This version of the doctrine (unlike some others) neither presupposes nor implies that any form of harm is absolutely wrong. It does presuppose that some harms stand in need of justification.

Traditional formulations of the doctrine of double effect apply it to predictable harms, but the doctrine can be applied to risk. Consider a teenager who dares a peer to drive at a high speed on a curvy, narrow road. This teenager might not wish for the driver to crash, but they intend for the driver to be in danger. The danger of a crash is the point of the dare. The doctrine of double effect implies that there is a moral difference between a dare and an invitation to take a long road trip at an ordinary speed. The total risk of the road trip might be the same as the risk of a short, reckless drive. Because the dangers of the long drive are merely foreseen, not intended, and they are more readily justified. Merely foreseen risks are more readily justified.

In a dare, the risks of an activity are valued for their own sakes. The doctrine of double effect also speaks against risks that are taken as means to ends. Consider a scientist who exposes healthy volunteers to a dose of radiation to study the effects of this dose on disease incidence. The very fact that subjects are exposed to risk is a means to the researcher's end of scientific knowledge. Contrast this with a CT study on healthy volunteers with the aim of obtaining imagery for research purposes. Here, the researcher foresees the risks of radiation exposure, but the risks themselves are not means to the researcher's ends. The doctrine of double effect implies that merely foreseen risks associated with radiation exposure are easier to justify than intended risks. The study of the harmful effects of radiation exposure would have to have a very great prospect of benefit to be justified, according to the doctrine. A lesser benefit would justify a CT study whose risks are merely foreseen. Another example of merely foreseen risk is the risk associated with a typical surgery. Surgery involves risk to the patient, but the fact that the patient is exposed to risk is not a means to improving the patient's health.

The doctrine of double effect is admittedly controversial. Consequentialists and some non-consequentialist ethicists, such as Thomson and Scanlon, doubt that the motives of an agent bear on the rightness or wrongness of an action.[16, 17] But the standard criticisms of the doctrine of double effect themselves face powerful criticisms[15]; the above formulation of the doctrine avoids the Thomson-Scanlon criticism. Several rationales for the doctrine have been offered.[18, 19, 20, 21] Arguably, the doctrine of double effect is central to the Kantian ethical tradition, as it is an implication of the Formula of Humanity: "So act that you use humanity, whether in your own person or in the person of any other, always at the same time as an end, never merely as a means." [22] To treat someone as a mere means is to pursue one's purposes by doing someone an



injury to which they could not rationally consent.[23] Only intended harms and risks can fall afoul of the “mere means” prong of the Formula of Humanity. If an act does or could do harm that is not a means to the agent’s ends, the act may still be wrong; it may involve a failure to treat someone as an end. The requirement to treat people as ends is generally understood to be more flexible than the “mere means” principle; it gives rise to “imperfect” duties. On a Kantian ethical framework, then, intended harm or risk is more difficult to justify than merely foreseen harm or risk.

The question what harms one could rationally consent to is difficult. On the Kantian view, people should value the effectiveness of their agency above the satisfaction of ordinary preferences, in part because people should prepare to fulfill unpredictable future duties to others. A well-functioning body is necessary to the fully effective exercise of agency. People have reason not to consent to being seriously injured or intentionally subjected to a serious risk of injury as a means to the satisfaction of ordinary preferences.<sup>3</sup> When the very fact that a person is exposed to serious physical risk is a means to economic gain, the person is used as a mere means. When injury or risk is foreseen but not intended, on the other hand, the “mere means” prong of the formula of humanity does not apply.

### **3. DOUBLE EFFECT AND HAZARD PAY**

The doctrine of double effect entails that it is unethical to pay someone to take serious physical risks unless there is a good reason other than payment for them to take those risks. Suppose that researchers invite healthy subjects to volunteer to get CT scans. Subjects’ only compensation is the knowledge that they will have contributed to a research project with

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<sup>3</sup> Intentional infliction of injury could be justified on other grounds, such as self-defense.

potential scientific and social value. The health risks of radiation exposure are neither the subjects' end in participating in the study nor a means to their end. That radiation exposure could cause cancer plays no role in helping to bring about the subjects' (and the researchers') end of advancing science. The doctrine of double effect is silent about the moral status of researchers' decision to invite subjects to enroll.

Now suppose that researchers invite healthy subjects to volunteer for a CT study, and they offer to pay enrolled subjects for the risks associated with radiation exposure. This payment is explicitly *for* the risks associated with the study. If subjects enroll in the study because they want this payment, then they take the risk of radiation exposure as a means to payment. The very fact that subjects are exposed to health risks is a means to their ends. Depending on what the study aims to accomplish, payment may not be subjects' primary end in enrolling. If the study could contribute to a socially valuable scientific advance, subjects could reasonably enroll for the sake of this advance (perhaps while accepting or even demanding payment as compensation for the risks they undergo).<sup>4</sup> If this is subjects' reason for enrolling, the risks of research will be foreseen side effects, not means to subjects' ends.

Do researchers act wrongly in offering prospective subjects hazard pay for participating in the CT study? The answer depends on what reasons subjects could reasonably have for enrolling. Suppose that the CT study has no prospect of making a socially valuable scientific advance, and the researchers know this. Then subjects could not reasonably enroll for the sake of contributing

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<sup>4</sup> These subjects could demand payment to avoid exploitation but not to compensate for what Millum and Garnett call "coercion as subjection" [24] since they share the researchers' aim. Acceptance of compensation does not imply that compensation is a subject's primary reason for participating. Compare: someone could agree to help a friend move into a new apartment on condition that the friend provide snacks.

to science. The only reasonable motivation for enrollment is payment, and the payment is compensation for taking a health risk. The very fact that subjects are exposed to risk is a means to their end, getting paid. Furthermore, since there is only one reason subjects could have for enrolling in the study, researchers implicitly endorse this reason for enrolling in the study. Presumably the researchers intend what they intend for subjects to intend. So the researchers intend that subjects intend to undergo risk as a means to the end of receiving hazard pay. (The researchers thereby fall afoul of the doctrine of double effect. One needs special justification ethically to intending for the very fact that people experience physical risk to be a means to an end. That justification is absent. Thus, it is unethical for researchers to pay volunteers for a CT study that has no prospect of contributing to a socially valuable scientific advance. The problem is not merely that the researchers would be wasting resources. They would also be using human subjects as mere means.

Matters are different if subjects could reasonably enroll with the primary end of advancing science. Then subjects could enroll while foreseeing but not intending the risks of research. Subjects could do this while accepting or even demanding compensation for their participation. Of course subjects could also enroll primarily for the sake of the hazard pay, and subjects who do this will intend risk to themselves as a means to an end. But the researchers need not endorse this reasoning, and they could recruit subjects without intending that any of their subjects reason in this way. Thus, researchers can offer hazard pay without using subjects as mere means if their study has sufficient potential social and scientific value.

#### 4. IMPLICATIONS

The doctrine of double effect supports a social benefit requirement in research. Paying subjects to participate in research that involves serious health risks is ethical only if subjects could have a reason other than payment to enroll.<sup>5</sup> The prospect of contributing to a socially beneficial scientific advance is the only good reason, other than payment, to enroll in a study that presents net risk to subjects. So, if a study involves serious risks to subjects, and the study presents net risk to subjects overall, the study must have a prospect of social benefit.

It is important to acknowledge two limitations in this conclusion. First, it only applies to research that poses serious risks of death, injury, or suffering. The increased cancer risk from a CT study may be considered a serious risk. The doctrine of double effect does not support a social benefit requirement for minimal risk studies. Some studies are classified as more than “minimal risk” because of temporary discomfort exceeding the discomforts of daily life or ordinary medical examinations, not because of long-term health risks.[25] It is at best unclear whether the doctrine of double effect supports a social benefit requirement for such studies. Second, the social benefit requirement defended here only applies to net risk studies in which subjects are compensated. It does not present an objection to studies in which the prospect of medical benefit outweighs or approximately equals the risks of participation. In such studies, any payment offered is for subjects’ time and trouble, not for risks they undergo.

The argument of this article has a further implication for Phase I drug trials and other safety studies that use healthy volunteers. In a study of the safety of a new intervention, the fact

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<sup>5</sup> Ancillary medical benefits, e.g. treatment or screening that is not itself part of the research procedure, may be counted as a form of payment here.

that volunteers are exposed to risk is the point of the study. If the very fact that people are exposed to serious risk is a means to one's ends, one acts unethically unless one realistically hopes to achieve a *very* great good. Dangerous safety studies are thus justified only if the prospect of social benefit is great. Normally, researchers designing safety studies should ensure that the study does not pose a significant risk of death or serious long-term injury.

One might worry that the argument of this article has implausible implications for the ethics of employment. But the doctrine of double effect permits employers to hire people for dangerous jobs and to offer hazard pay as compensation for risks. For such jobs to be ethical, there must be a good reason other than hazard pay for workers to consider these jobs desirable. People can reasonably choose to work as firefighters because of the social value of the work. They may at the same time demand hazard pay as compensation for the risks they undergo. By contrast, there is no reason other than payment to work in a dangerous mine tediously extracting gemstones whose only purpose is adornment. Helping others to satisfy their desire for a status symbol is not a sensible reason to make an altruistic sacrifice. Offering jobs in such a mine, with a wage premium to induce people to take these jobs over safer or more socially valuable alternatives, would be inviting people to treat the very fact that they are exposed to risk as a means to financial ends. To claim that such jobs are unethical is reformist but not radical. It supports the dominant view in medical research ethics: social benefit is required for hazardous activities to be ethical.<sup>6</sup>

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<sup>6</sup> This work was inspired by conversations with Alan Wertheimer during my fellowship at the National Institutes of Health in 2010-2012. I am grateful for his thoughtful mentorship.

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