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Kennedy Institute of Ethics Journal, Volume 29, Number 4, December 2019, pp. 305-331 (Article)

Published by Johns Hopkins University Press
DOI: *https://doi.org/10.1353/ken.2019.0028*

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ABSTRACT. In phase I clinical trials, healthy volunteers are dosed with investigational drugs and subjected to blood draws and other bodily monitoring procedures while they are confined to clinic spaces. In exchange, they are paid. These participants are, in a direct sense, selling access to their bodies for pharmaceutical companies and their associates to run drugs through. However, commodification is rarely investigated as an ethical dimension of phase I trial participation. We address this gap in the literature by bringing the voices of phase I healthy volunteers into conversation with philosophical perspectives on body commodification. Querying the intersection of commodification and phase I clinical trials illuminates important features of healthy volunteers' experiences, disentangles commodification from a dominant narrative about exploitation, and brings focus to the question of what, if any, market norms will best protect the multiple ways in which healthy volunteers' welfare is impacted by clinical trial participation.

INTRODUCTION

In phase I clinical trials, healthy volunteers are dosed with investigational drugs and subjected to blood draws and other bodily monitoring procedures. In exchange, they are paid. Healthy volunteers are, in a very direct sense, selling access to their bodies for pharmaceutical companies and their associates to run drugs through. In his ethnographic study of so-called professional guinea pigs, Roberto Abadie writes, "Paid volunteers are well aware of the demand for an idealized, perfectly healthy volunteer. They also realize that their body is a valued commodity in clinical trials research" (2010, 25). It is perhaps surprising, then, that commodification is little discussed in the bioethics literature on phase I healthy volunteer research. The issue is sometimes raised provocatively as a problematic

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for considering clinical trial participation as akin to employment but left unexamined (see, e.g., Elliott 2008). Where it is discussed, it may be dismissed as an issue without any traction, since payment seems necessary to incentivize participation in phase I research, which is considered a crucial part of drug development (Stones and McMillan 2010; Różyńska 2018). Alternatively, the ethics of commodification in clinical research may be usurped by discussions of moral problems with markets that are widely accepted—though hard to characterize—such as exploitation (Wertheimer 1996, 102–107; 2011, 191–254).

Commodification of the body, however, has a long history of interrogation in philosophy, particularly as regards women's bodies (Satz 1992; 1995; Anderson 1990; Radin 1996). Even within bioethics, commodification has received the most focused attention when it comes to the question of markets in women's reproductive labor or materials (Ballantyne and de Lacey 2008, 159–160; Holland 2001). Why, then, has commodification been so little investigated when it comes to phase I trial participation? The fact that most phase I healthy volunteers are men stands out as a potential reason for this omission, given that men's bodies are less frequently the focus of examinations of commodification. A more subtle issue has to do with the fact that many bioethics practitioners strive to offer concrete solutions to ethical problems in biomedicine. In that context, the hotly contested moral valence of commodification may give pause to those considering its significance. Within philosophy, for example, there is disagreement both over what in particular (if anything) is wrong with markets in the body as well as what (if anything) ought to be done to counteract these markets (Satz 2010; Anderson 1993; Radin 1996). Thus, commodification might seem worth flagging as an ethical concern, but not developed in terms of its implications for participants in phase I trials or research endeavors more broadly (see, e.g., Grady 2005). In sum, without a settled sense of whether or how commodification is ethically problematic, it may appear a stretch to attend closely to its nuances in biomedical research.

We argue differently. First, we show that healthy volunteers readily engage questions about body commodification and their involvement in phase I clinical trials in ways that shed light on their participation, regardless of whether they perceive these practices as ethically neutral, problematic, or salubrious. Thus, at a practical level, investigating how commodification intersects with phase I trials illuminates the experiences of healthy volunteers. Second, healthy volunteers' moral concerns about

commodification are typically oriented to broader discomfort with some types of exchanges, rather than only being concerned with the amount of compensation. Within bioethics, it is therefore important to consider commodification in phase I trials distinctly from exploitation, or to bolster views of exploitation that reach beyond the typical characterization as unfair exchange. Third, healthy volunteers' perspectives on commodification of the body mirror philosophical disagreements over these issues, but also give empirical credence to some theoretical contentions and help to identify feasible routes to addressing the body commodification involved in phase I participation. To develop these arguments, we first present some of the core theoretical issues at stake in questions of commodification. We then examine the views of healthy volunteers on whether they are "selling or renting" their bodies through their phase I participation. Finally, we consider how these views intersect with the philosophical perspectives discussed.

PHILOSOPHICAL BACKDROP

A core ethical issue in the commodification literature hinges on the marketization of the body. The philosophical literature on commodification features robust disagreement over the legitimate *scope* of markets, the *reasons* why some markets may be problematic, as well as what should be *done* about such markets. At the most basic level, theorists differ over what falls outside the appropriate scope of market norms. As Debra Satz aptly notes, "the market system institutionalizes the idea that, potentially, anything might be traded for anything and *anyone* might enter into the great trading game" (2010, 23). Although most debates about commodification focus on a limited number of markets in what Margaret Radin (1996) terms "contested commodities," Marxist theorists object more globally to commodification of labor, while some libertarians maximally embrace markets. Jason Brennan and Peter Jaworski claim, for example, "if you can have it for free, you may buy it, and if you may give it away, you may sell it. There are no inherent limits to markets, only incidental limits" (2016, 156).

Broader questions about the appropriate scope of markets aside, theorists detail diverse, though overlapping, reasons why commodification of the body and markets in body uses, parts, and products might be wrong. One significant line of reasoning focuses on what sorts of goods and activities can legitimately be subject to market norms—and in what spheres (Walzer 1983; Anderson 1993; Sandel 2012). In this vein, Elizabeth

Anderson argues against markets in women's sexual and reproductive capacities, and writes, "Higher, shared, and personal ways of valuing goods require social constraints on use. We can express these valuations only in social spheres governed by non-market norms" (1993, 164–65). Another set of arguments is focused on how markets promote or disrupt distributive equality (Dworkin 2000; Arneson 1992). Richard Arneson, for example, advocates for allowing commercial surrogacy on egalitarian grounds and suggests that "a concern that some people are forced to choose their lives from an unfairly small menu of option is a reason to expand not restrict the range of options from which these people must choose" (1992, 159). A third line of reasoning focuses on how markets promote or disrupt relational equality. Satz discusses what she terms "noxious" markets, including those in human body parts and sex. Disagreeing with Anderson, Satz asserts, "A major problem with noxious markets is not that they represent inferior ways of valuing goods … but that they undermine the conditions that people need if they are to relate as equals" (2010, 94). Relational equality in Satz's view requires such background conditions as social rights, liberties, and the attainment of some basic goods and resources like education (2010, 99).

Even when theorists agree that some types of body commodification are problematic, they may disagree on what should be done to address the issue. These differences may line up with what each theorist thinks is wrong with a particular type of commodification. Proposed recommendations include those that are themselves market solutions as well as banning some types of markets. For instance, on one hand, enlarging rather than restricting the scope of the market or redistributing goods within markets may address some distributive justice concerns. On the other hand, markets perceived as illegitimate because of what is for sale are likely to be met with a call for abolition. A third approach might redress problems through increased market regulation. It is possible, for example, that if a problem with a market is its tendency to exploit vulnerabilities, the market may be tightly regulated—or differently approached—rather than banned altogether. This third way is particularly relevant for the case of phase I trial participation as we shall address later.

Commodification of the body, then, is contested in terms of when it occurs, whether and why it is problematic, and what can be done to ameliorate problems it might generate. In their respective works, both Satz (2010) and Radin (1996) call for attention to the contours of *specific* forms of commodification. Satz does so by way of building

her multi-dimensional theory of noxious markets, which vary along parameters of vulnerability in participation, weakness of agency, and harmful outcomes for individuals and/or society (2010, 9). Radin takes a more thoroughgoing case-by-case approach to the question of when and why commodification is problematic. Radin's "pragmatic" integration of concerns for personhood and human flourishing affirms some limits on markets and at the same time holds that "no one theory is suitable for all cases of contested commodification" (1996, xii). In keeping with these grounded approaches to specific markets in the body, we consider the implications of commodification in phase I clinical trials by reporting on how healthy volunteers perceive the use of their bodies in testing new pharmaceuticals. Querying the intersection of commodification and phase I clinical trials illuminates the ethical significance of the topic to healthy volunteers' experiences, emphasizes the importance of commodification as a moral issue distinct from exploitation understood as unfair exchange, and helps to interrogate various approaches to body commodification that are applicable in the space of phase I clinical trial participation.

METHODS

We draw upon in-depth qualitative interviews with healthy volunteers in which they were asked their views on whether their participation in phase I trials is a form of commodification. This inquiry is part of a longitudinal study for which we enrolled 180 people who were participating as healthy volunteers in phase I trials at seven U.S. research clinics. The purpose of the study was to investigate how healthy volunteers' perceptions of the risks and benefits of phase I participation, and their decision making regarding trial enrollment, might change over time based on their experiences in phase I trials or changes in their personal situations (for more details about the study methods, see Edelblute and Fisher 2015 and Fisher et al. 2018). As part of the design of our study, we randomized 20% of our sample to a "control" arm to be able to assess whether we had an intervention effect on the "full participation" arm. The key difference between the study arms was that we conducted only two interviews with control participants—one at enrollment and one three years later—while we conducted five interviews with those in the full-participation arm—one at enrollment, then others six months, one year, two years, and three years later.

As with other studies of healthy volunteers (Fisher 2015; Fisher and Kalbaugh 2011; Grady et al. 2017), our sample was demographically diverse but included primarily men (73%) and racial and ethnic minorities

(68%). Most participants were over thirty years old (78%) and un- or underemployed (75%). Nearly half reported a household income of less than $25,000 per year (46%). As is typical of healthy volunteers (Tishler and Bartholomae 2003; Elliott 2008), the vast majority had participated in at least one previous phase I trial (79%), and more than half of our sample had participated in at least five studies (51%). Thus, their reflections on phase I trials typically included an array of experiences participating, rather than the single trial in which they were enrolled when they joined our study.

As part of our interest in commodification, we developed questions that could elucidate this concept for the six-month interview with the 145 healthy volunteers in our full-participation arm. We asked: "Some people have compared study participation to selling or renting your body. As someone who participates in studies, how do you react to this view of what you are doing?" The interview guide also included a follow-up probe: "In what ways would you say that your body or health is a commodity to be sold?" To track responses to these interview questions, we used the code "Body as Commodity" as we coded interview transcripts. We also applied this code to unprompted instances in the six-month, one-year, two-year, and three-year interviews in which participants described their participation in clinical trials as like selling or renting their body or otherwise involving a transactional use of their body.

We successfully completed 131 six-month interviews (90.3% of those attempted), and 130 of those participants were asked the commodification question. Unprompted reflections on commodification were quite rare across the four waves of interviews for which we coded this theme. We found 74 unprompted instances of this theme in 558 interviews with our participants. This indicated to us that it is not the typical lens through which healthy volunteers understand their phase I participation. Yet, the prompted responses to the six-month interview question, as illustrated below, nonetheless reveal the important work that the concept of commodification does when individuals directly engage this perspective about the use of their bodies in paid medical research.

HEALTHY VOLUNTEERS' REFLECTIONS ON COMMODIFICATION

Queried Reflections

In response to our direct question about "selling or renting" their bodies for phase I trials, we found participants' answers could be broadly categorized in two ways: either denying that their participation can or should be

characterized in that way or else acknowledging commodification. Healthy volunteers' primary denial strategies included talking about (1) the societal value of clinical trials, (2) trial compensation as a legitimate source of income, (3) trial compensation as based on time rather than use of participants' bodies, and (4) the safe and/or informed nature of their participation. Alternatively, healthy volunteers acknowledged how clinical trial participation could be a form of body commodification by justifying or even embracing this view. They did so by (1) simply agreeing that their trial participation was to a significant extent a form of body commodification, (2) emphasizing the risks of enrolling in phase I trials, and (3) normalizing commodification by comparing it with other common ways of selling or renting one's body.

Participants' responses clustered fairly evenly between the denying and acknowledging categories, but the most dominant themes in each were respectively denying commodification because of clinical trials' societal value and simply agreeing, whether reluctantly or with positive affirmation, that clinical trials were a form of commodification of the body. The weakest theme was the denial strategy of appealing to payment for participants' time rather than use of their bodies. Importantly, some participants voiced both denial and acknowledgment when discussing commodification and some mobilized multiple themes within each category. We develop and illustrate each denial and acknowledgment subtheme in more detail below.

Denial strategies

I) Not commodification because of societal value of participation

Many healthy volunteers appealed to the socially valuable purposes of clinical trials as a means of rejecting the language of commodification regarding their study participation. A white man in his fifties who had done sixteen trials stated, "[Commodification is] the wrong way of looking at it. You know, you're trying to do something that's gonna be beneficial to some people in the future" (F1445). A Mexican immigrant in her forties who had done four trials was even more adamant about the distinction between selling one's body and contributing to the social good: "You're actually helping somebody out there. You know, somebody that might have needed that medicine. I don't think selling your body would be helping or benefiting. … You know what I mean? Like, I don't think that people that really do sell their bodies, they … [do] help anybody out" (F3315).

Importantly, appeal to the societal value or impact of clinical trials was typically not an expression of altruism. Rather, participants understood their personal financial benefit as congruent with the social benefit of the larger research enterprise. A black man in his thirties who had done seventeen trials explained, "You could help to break through a medicine. … You can earn a decent amount of money on the side in the process, so on and so forth, but I wouldn't say rentin' my body. I don't know. I just wouldn't use that analogy" (F1439). An immigrant from Nicaragua in his twenties who had done five trials echoed this view: "I don't think so nor would I describe it that way [as selling or renting one's body]. For me, it's as much a benefit for oneself as it is for being able to help other people" (F3317, translated from Spanish).

While some participants indirectly inferred that selling one's body would be an unethical way to make money (such as the Mexican woman above who worried that people who actually sell their bodies are not helping others), other participants who appealed to the societal purposes of clinical trials were more direct about the negative moral implications of body commodification. A white woman in her twenties who had done one trial proclaimed, "That's crazy talk. It's science. I mean, selling, … I guess that that expression of selling your body, I think that more is like donating your eggs or something, but … I don't feel like you're doing anything morally wrong" (F2106).

II) Commodification less apt because of legitimacy of trial compensation

When asked whether they were selling or renting their bodies through their clinical trial participation, many healthy volunteers rejected this view citing how study compensation is "legal" income and/or participation was tantamount to a job. An immigrant from Russia in her thirties who had done about fifty studies observed, "You're doing studies because you need money … because you have bills to pay. And the study has nothing to do with your body as a commodity" (F2410). This perspective may be puzzling considering that people who sell or rent use of their bodies are also doing it for the money. However, a more comprehensive look at participants who made similar comments makes apparent that, for them, clinical trial payments are legitimate, particularly when contrasted with illegal markets in the body. A black woman in her fifties who had done seven trials got right to the point: "I think it's legitimate work; it's legal. I wouldn't compare it to prostitution or anything like that. I can't get arrested for doing a study. I pay my taxes, you know. So, I don't know. I

don't feel bad about it" (F1450). A Hispanic man in his forties who had done over fifty trials conceded, "You know, I mean, if that's what you want to call it [selling or renting one's body], then that's what you're calling it, but to me, it's a job" (F3463).

III) Not selling body but time

Perhaps surprisingly, given research oversight support of this narrative, very few participants refused the label of commodification by arguing that compensation was for their time rather than use of their bodies. One such participant was a black man in his thirties who had done four trials. He provided a clear exposition of this perspective from the vantage point of a healthy volunteer:

> [It's] not really renting your body; it's your time. Because if you ever look at how much people make, they always saying, "Okay, for every day you stay here, we giving you this." It's the time. It's time. So, I'm looking at the time. If you don't want to stay here, if you want to leave—and they say that—you can leave. Ain't nobody restricting you; ain't nobody locking you up. You know, it's a contract, really. So, I don't see it as really renting my body. I see it as like just doing the contract. (F2202)

This particular appeal to payment for the participant's time rather than rental of his body appears to also set up a parallel contrast between a voluntary contract and a coerced use of a participant's body.

IV) Not selling or renting because safe and/or informed

A more common refrain from participants who distanced themselves from commodification of their bodies was to emphasize the relative safety or informed nature of their trial participation. For example, a white man in his forties who had done five trials reflected, "I thought that way at the beginning [as selling or renting the body], but [I changed my view] once I understood how it works, actually how safe they are and how fast of a time period drugs are in and out of your system. There's no lasting effects" (F1321). To refute commodification, a black man in his twenties who had done eight studies focused on the scientific purpose of clinical trials as well as participants' power of consent:

> I would just look at it as being compensated for testing a drug, not renting my body. I would say that you're giving them information about the drug in your body, you know, just giving them data. I mean, 'cause they don't have a real, like—I don't know—they're not, like, doing things they want

> with your body, 'cause you have, you know, full power of what goes on. And you can tell them that you don't want to do this or do that. (F2305)

Acknowledging strategies

I) Reluctant or positive agreement

Many healthy volunteers, when directly asked whether they were selling or renting their bodies through their clinical trial participation, simply agreed that this is so. Their modes of agreement ranged widely, however. Some participants easily accepted the terms of the question. According to a multiracial man in his twenties who had done ten trials, "I only see it as a financial thing, so to me, it's basically selling because they're giving money and I'm giving them something in return, so it's like a financial transaction, I suppose" (P1402). Some participants accepted only after some consideration that their exchange with phase I research clinics was a form of body commodification. This was the case for a black man in his twenties who had done twelve trials: "No, I don't think it's selling my body. I think—Yeah, actually it is, actually it is. [laughs] But, oh shoot, it don't bother me" (F2416). Others acceded to only some part of the commodification framing. A Salvadoran immigrant in his fifties who had done one trial related, "I think it is like renting your body. … I don't see it as selling it because it isn't a lot to sell it, you understand me? I think it's like they're paying a rent to get permission to use your body for the study that they're doing" (F3112, translated from Spanish).

Some participants were rueful about being engaged in an activity that was like selling or renting use of their bodies. A white man in his fifties who had done over sixty trials expressed, "Selling or renting your body? Yeah, I mean, I see it as an evil compromise. It's kinda weird. I do studies, but I do not believe in pharmaceutical companies whatsoever, at all" (F1466). Along similar lines, a Hispanic man in his thirties who had done ten trials conveyed the following:

> I'm also selling—like, I don't wanna say I'm selling my integrity and stuff, but I mean, you know, it's like boundaries you're willing to let people cross, you know, for money. … Oh gosh, it's like, having these little realizations about yourself that aren't always pleasant, you know? (F3459)

Other participants, however, wholeheartedly embraced the idea that their trial participation was a form of body commodification. A multiracial

man in his twenties who had done two trials summed up this perspective: "I feel like my body is one of the best commodities just 'cause I'm really healthy, and like what better way to see how stuff works than on like a test subject whose health remains constant?" (F2108). A white woman in her thirties who had done nine studies noted that she had not previously considered whether clinical trial participation was a form of selling or renting her body, but she nevertheless was enthusiastic about the idea:

> Well, since I am healthy, I guess that is a really good way to look at it because they're kind of borrowing my healthy body to use, you know, in their little study and kind of mess with it and see what it does. So, I mean, considering I'm getting paid for it—and quite well [paid] a lot of times—I would say it definitely is a commodity. Never thought about it like that. (F2408)

II) Like selling or renting because of trial risks

The flip side of healthy volunteers rejecting a narrative of commodification based on the safe and/or informed nature of their participation was manifest in those who believed that trial participation was like selling or renting one's body because, or if, it is risky. A black man in his thirties who had done six trials indicated, "So I guess it kind of is like selling your body because you don't know if it's safe. Is it safe or is it harmful? And if … it's going to kill you or if it's not, [laughs] you know" (F1215). Another participant, an immigrant from Nepal in his forties who had done eleven studies, stated, "I feel sometimes like that too. Selling my body to big drug companies." When prompted by the interviewer to describe in what ways his body was a commodity, this same participant homed in on study payment relative to potential future harms, professing, "Well, there's a lot of unknowns that we are taking, and in that sense, you know, the money they pay is not compared to what we have to go through in the future or whatever" (F2407). Because of these trial risks, a black man in his twenties who had participated in one trial preferred the idea that his health, not his body, was the commodity for sale. He opined, "I would say like selling your health or trading your health for money. That's a better way to look at it. … Are you trading your health for money? [Yes.] Because you can get sick and you will get paid" (F1122).

III) Normalizing commodification

A common refrain among healthy volunteers who acknowledged how clinical trial participation commodifies the body was to normalize this

practice by comparing it to other everyday forms of commodification. Participants made comparisons to everything from professional sports and modeling, to hedge fund management, to construction work. One participant, a black man in his twenties who had done nine trials, made a global generalization regarding commodification and paid work: "I mean, honestly, if you go and get a regular job, you're … selling your body because you got to be there. Your person has to be there. You can't get paid if you're not at work. So, I mean in reality, we're all selling our body" (F2302).

Some healthy volunteers who normalized commodification of the body had very positive views about this take on their clinical trial participation. For example, a multiracial man in his thirties who had done over thirty trials declared, "But as far as using my body as a commodity, absolutely it is. You know, LeBron James uses his body as a commodity, you know, so—and he's my favorite athlete, so I'll mention him—but that's absolutely, you know, what I'm doing" (F2411). A white woman in her thirties who had done three trials extolled body commodification more broadly:

> I feel like it's my body to do as I please with, and I don't feel like I'm being reckless. So, if I am renting my body, then I'm happy to do that. And I also rent my time and my thoughts and my thinking to other people when I do other kinds of work, so it's not necessarily different. (F2309)

Despite normalizing how bodies are routinely commodified, others held negative views of the phenomenon, not only in their clinical trial participation but also in life generally. A black woman in her forties who had done six trials asserted the following:

> I feel like, you know, you go to work every day, and you've got to have somebody telling you what to do every day when you go to work—somebody's telling you what time to punch out, what time to punch in, if you're gonna get your vacation [time], if you're not gonna get vacation, you know, if you're gonna get health insurance, if you're not gonna get any health insurance. So what's the difference? … All of us are renting our bodies. (F3434)

A white man in his forties who had done twenty trials explicated the tie between the general sentiment of commodification and broader dissatisfaction with work:

> So whether it's a lab rat [a term sometimes used for phase I participants], whether it's an IT professional, whether it's an accounting professional, if

> they don't like what they're doing—it doesn't matter what they're doing—they're still going to pretend that they're being—excuse the expression—whored out. (F2413)

Participants' Reflections on Clinical Trials and "Prostitution"

This last participant also draws attention to the common, and perhaps unsurprising, comparison that healthy volunteers made between clinical trials as a form of body commodification and sex work or prostitution, which is currently illegal in most jurisdictions in the U.S. This theme arose in participants' unprompted discussions of commodification as well as in response to our interview questions about selling or renting one's body in clinical trials. As an example of an unprompted comment, one Hispanic man in his thirties who had done ten trials mobilized a sex-work analogy to explain why he is secretive about study participation: "No, yeah, definitely it's embarrassing. [It's] Like I'm a girl that works in a brothel and I told my family I work at a dress shop. Totally, I never tell anybody. I mean, I probably never will, you know?" (F3459, three-year interview).

When explicitly asked about commodification and clinical trials, the tie to sex work was articulated most often by participants who rebuffed the idea they were selling or renting their bodies because of the societal value of clinical trials, but the theme came up with participants in both the denying and acknowledging categories. Interestingly, the comparison even manifested in participants' attempts to normalize body commodification. For instance, a white man in his fifties who had done fourteen trials insisted, "I would say that, what area in life don't we prostitute ourselves? You know what I mean?" (F3431). However, most participants were more literal when they conjured sex work in response to our questions, and for many, the comparison served to reject the lens of body commodification. For example, a black woman in her forties who had done six trials protested, "I mean, renting my body or letting someone use my body? To me, that sounds like a prostitute or something; I'm not having sex with anyone [in a clinical trial]" (F3434). A black Hispanic man in his forties who had done one trial used his gender to disassociate himself from such practices. He pointedly said,

> They don't have male prostitute. If they do, I have never met one. But, you know, female prostitute, they sell their body, you see. They selling their body, you know. … You doing something [in clinical trials] to better the world. As opposed to a prostitute. She's not bettering—she's not even bettering herself. She's degrading herself, you know. (F1126)

Occasionally, participants used the parallel to sex work as the basis for understanding the transactional nature of clinical trials. A black man in his twenties who had done over twenty trials presented a nuanced viewpoint on the issue:

> It's got some of the same characteristics of being a—I hate saying "prostitute"—but being a prostitute, 'cause it's sort of like you're just a number here [in a clinical trial] … They don't know you, [that is] who you are as a person. It's just like you're coming in and getting the money. You're a number or a name, and you're going. … The only thing that's different is the positives about it. The negatives are all still about the same, [such as] damaging your body—or you could be, you know what I mean? But the positives are different. The positive is you can be helping for a future drug that could help someone. And also, you claiming it on your taxes is legal. So, that's why I say it's probably different, but the negatives are kind of the same. (F2414)

A white woman in her forties who had done thirteen trials rhetorically thread the needle between these perspectives, giving a tongue in cheek narrative on the issue and comparing her clinical trial participation with both sex-work roles of "pimp" and "prostitute":

> I used to kind of, I'd maybe use the phrase sometimes "pimping my body for science." But it's also doing some good, so [laughs] I'm sure prostitutes come up with a lot of justifications for what they do too. [laughs] Oh goodness, yeah. They're helping these men stay in their marriages. [laughs] Who knows, who knows what they come up with. Yeah, "I'm doing a service." (F2421)

Unprompted Reflections

Participants who raised issues of commodification without prompting by an interviewer typically did so to describe or interrogate the nature of their clinical trial participation. Unlike the queried reflections, the theme was raised to assert that they were in some sense engaged in body commodification. Some participants matter-of-factly equated payment for trial participation with granting access to or selling their bodies. A multiracial man in his thirties who had done over twenty trials responded to a question about whether he would ever participate in uncompensated studies by stating, "I'm not working for free. I'm not giving up my body, you know? I'm giving up my body, and that requires payment" (F2406, three-year interview). Another participant, a black man in his fifties who also had done over twenty studies, described the transaction this way: "You

get paid for your blood. And you go around and look for another [study] 'cause, you know, you're an independent contractor; you're selling your blood to the highest bidder" (F1465, two-year interview). These comments in many ways mirror how participants acknowledged commodification when prompted through our interview questions.

Depending on the participant, other unprompted comments about commodification were cast as either a positive or a negative feature of their clinical trial involvement. A black man in his thirties who had completed thirteen studies framed commodification as motivational in the context of his serial trial participation:

> I take good care of my body. My body's my business. As long as I'm healthy … my business is gonna be successful. When I start not taking care of my business or whatever, my body and stuff, it's gonna start sliding off. [Then] I'm not making that much money [and] I'm not getting that many jobs. You know, same thing. It's a commodity, so. (F2202, three-year interview)

In contrast, a Mexican immigrant in his forties who had also completed multiple trials negatively viewed this type of transaction. After being asked about sharing information about his study participation with others, he stated, "Like I said, it is not something that I am really proud of because, practically, you are selling yourself for them to do what they want. They inject you, take out your blood, you sell yourself for money there [at the research clinic], and in the long run you think, 'It's [too] little money, pay me more'" (C3409, three-year interview, translated from Spanish). Thus, participants' unprompted comments about commodification emphasized the centrality of their bodies in a financial exchange with the research clinics conducting phase I trials. These comments took on more of a "business" orientation than when participants were queried about renting or selling use of their bodies.

DISCUSSION

Healthy volunteers readily engage in reflection about body commodification. They both offer unprompted insights on their experiences with phase I clinical trials as a type of body commodification and also are responsive in myriad ways when queried about their perspectives on the issue. In so doing, they illustrate the spectrum of views that can be brought to bear on whether and how phase I trials are commodifying. Healthy volunteers' responses to a question about selling or renting their bodies in trials generated both denying and acknowledging responses that offer insights

into what commodification of the body might mean and how it is morally valenced. Specifically, in their reflections on commodification, participants highlighted the societal value of clinical trial participation, the legitimacy or the legality of the economic exchange, the role of risk in commodification, and banality of commodification because of its prevalence in everyday life. These frameworks for understanding commodification and clinical trial participation underscore the interpretive flexibility that enables the concept to be perceived as negative or positive, sometimes by the same individual. In addition to that interpretive flexibility, as we address here, putting phase I participant perspectives into conversation with bioethical and philosophical perspectives on body commodification sheds light on how we might reconsider the connection between commodification and exploitation as well as what lessons we might draw for managing markets in healthy participant bodies.

The Moral Valence of Commodification for Healthy Volunteers

That healthy volunteers acknowledge, resist, and even embrace the explanation of their participation in clinical trials as body commodification mirrors the philosophical disagreement over the extent to which markets in body use or products are problematic. More subtly, in some cases the explanations participants offer for agreeing or disagreeing that they are engaged in a commodifying exchange may offer some insight into their perspectives on the ethics of body commodification. For example, the purported societal value of phase I trials does not obviously negate a sale or rent of the use of one's body, just as the sale of one's blood or gametes does not itself undermine a positive goal of saving a life or achieving a pregnancy for another individual. Therefore, that healthy volunteers framed their clinical trial participation as socially valuable *in order* to undercut the claim that they were selling or renting use of their bodies may imply that they deemed body commodification to be suspect and, in some cases, explicitly ethically problematic. Some of these participants may endorse the theoretical perspective that specific markets in the body are ethically dubious. Such a conclusion would not, of course, necessarily undermine their claim not to be involved in such markets.

Similarly, the connection between risk and commodification is a tenuous one. Some healthy volunteers nonetheless used the explanation that clinical trials are safe to resist the notion that they were selling or renting use of their bodies, whereas others agreed to this formulation of their activities by describing the risky nature of their participation. Interestingly, however,

both viewpoints imply that body commodification is a potentially harmful form of exchange. Thus, for many healthy volunteers, *whether or not* they subscribed to the idea that they were selling or renting use of their bodies in phase I trials, the concept of commodification was largely associated with negative ethical or other harmful implications. This was also the case for healthy volunteers who thought commodification was a ubiquitous phenomenon rather than specific to phase I trials, but as they normalized the ways in which individuals sell or rent their bodies, they cast the process in a negative light. Such participants could perhaps be compared with theorists taking a generally negative stance toward commodification.

Yet other healthy volunteers did not categorize commodification as a negative or harmful activity. Specifically, those who normalized body commodification but also saw these exchanges as positive imply in their reasoning that there is nothing morally or ethically wrong with selling or renting use of one's body. Indeed, some even propose that it is an astute or rational way to use the resources one has available to earn income. This particularly came through in healthy volunteers' narratives in which they embraced clinical trials as a form of body commodification. These participants might be seen as endorsing the perspective of those theorists who prefer a liberalized purview of market exchanges.

Exploitation and Commodification in Phase I Trials

Whereas body commodification has been relatively ignored in the bioethics literature on phase I trial participation, concerns about exploitation, especially in the context of international clinical trials, have been on the rise (Hawkins and Emanuel 2008; Macklin 2004; Sofaer and Strech 2011). The relationship between commodification and exploitation is complex and disputed, and depends in part on how each concept is understood. Within bioethics, and in the context of payment to healthy volunteers, concerns about exploitation have largely been focused on the amount of payment offered for clinical trial participation with the idea that 'unfair' payment would be exploitative (Wertheimer 1996; Resnik 2003, 247; Phillips 2011; Largent and Lynch 2017). As Angela Ballantyne sums up, "Exploitation is about unfairness: specifically about the unfairness of the distribution of benefits and burdens between the parties to a transaction" (2008, 180). This way of understanding exploitation fits well with concerns about the implications of commodification for distributive justice, which is also essentially focused on how to promote fair distribution.

When asked about body commodification, however, phase I participants only rarely referred to the amount of money they earned—whether it was too low or how it was determined. Those who did refer to the amount they were paid sometimes did so in the context of their overall frustration with being in a position of having to sell access to their bodies to earn an income. While there is every reason to think that phase I participants are highly concerned about the amount of pay they receive and whether it is fair (Walker, Cottingham, and Fisher 2018), these specific concerns seem loosely connected to those evoked by ideas of commodification.

Another way of understanding exploitation, however, appeals to the problematic taking advantage of the less powerful party in a transaction, including a failure of appropriate respect for persons (Carse and Little 2008; Snyder 2012; Siegel 2008). This way of understanding exploitation has much in common with how Satz describes noxious markets, which "arise from weak agency, exploit the underlying vulnerabilities of the most vulnerable, or have extremely harmful consequences for individuals or their societies" (2010, 35). To be sure, not all noxious markets are forms of body commodification, nor are all forms of body commodification noxious. However, if certain markets in the body are concerning because the power differences between the transacting parties create conditions rife for illegitimate use of the vulnerable party, these specific forms of commodification may go hand in hand with exploitation as a failure of relational respect.

There is plenty of evidence that phase I trial participation has the potential to become a noxious market, especially along the dimensions of economic vulnerability and weak agency, particularly because it is a global for-profit enterprise (Fisher 2009; 2020; Petryna 2009). The majority of healthy volunteers are financially vulnerable individuals due to underemployment and membership in minority racial and ethnic groups (Cottingham and Fisher 2016; Monahan and Fisher 2015). They experience powerlessness in setting the terms of their exchanges with phase I clinics as payment for participation is not protected as a type of employment, even though many enroll serially and depend on clinical trial income to make ends meet (Walker, Cottingham, and Fisher 2018; Fisher and Walker 2019). To illustrate potential harmful consequences of these markets, past scandals in the commercial phase I industry include trials in which undocumented individuals were participating in run-down conditions and homeless alcoholics were recruited to test drugs in exchange for room, board, and pay (Evans, Smith, and Willen 2005; Cohen 1996).

While the connection between the commodifying aspects of clinical trial participation and these potentially exploitative conditions remains unclear, it is significant that for healthy volunteers, questions about body commodification were tied to themes that seem closely connected to issues of respect and interpersonal equality. In particular, when healthy volunteers addressed the connection between commodification and pay for clinical trial participation, they were concerned in part about being treated *as* a commodity—without a say in what happened to them or as an identifiable individual. Thus, in so far as exploitive tendencies are identified as a moral concern for body commodification in phase I healthy volunteer trials, it is important that we consider exploitation as a phenomenon associated not only with unfair transactions but also with relative powerlessness and disrespect.

Body Markets and Vulnerable Groups

Market norms may also be viewed as ethically fraught with regard to certain types of exchange regardless of exploitative tendencies. Paying healthy volunteers more money may fix a problem of an unfair exchange, for example, but not of the application of market norms where they do not belong. Some participants seemed to voice such broader ethical concerns about the nature of an exchange that involved the "sale or rent" of their body for use in clinical trials. Many also reflected on what they viewed as the associated stigma of such practices.

The widespread comparison that healthy volunteers raised between selling or renting their bodies in clinical trials and sex work is particularly telling in this regard. Although participants also referenced other forms of market exchange having to do with the body, especially selling blood separate from and within the context of clinical trials, the theme of prostitution was dominant. Within those discussions, sex work was conjured to illustrate the negative connotation of body commodification and its largely female enterprise. Some participants used this comparison to refute the notion that they too were selling or renting use of their bodies in clinical trials while others were quite matter of fact about the parallels between the two activities, even acknowledging how their clinical trial participation was akin to prostitution. How should we interpret healthy volunteers' views of their phase I participation through the lens of sex work?

The gendered aspect of commodification was especially salient in these findings. Beyond a focus on clinical trials, commodification has been raised

as an ethical issue in particular in regard to the use of women's bodies. At first blush, male-dominated phase I participation raises the question of how to understand the gendered sale or rent of one's body in such a context. Yet, healthy volunteers' persistent references and parallels to "prostitution" when asked about whether they were selling or renting use of their bodies in phase I trials indicate the important gendered construction of commodification. Crucial to this discussion is the fact that male healthy volunteers do not—merely as men—lack the kind of vulnerability that often motivates examination of commodification of women's bodies, since most are minority men with fragile economic trajectories (Cottingham and Fisher 2016; Fisher 2020). To unpack the ethical significance of healthy volunteers' perceptions of the ties between body commodification and "prostitution," we turn to a philosophical analysis of the issues at stake.

Margaret Radin in her work on contested commodities describes what she calls the "double bind" (1996, 123–130) of markets in women's sexual and reproductive activities. She writes

> If the social regime permits buying and selling of sexual and reproductive activities … there is a threat to the personhood of women, who are the "owners" of these "commodities." The threat to personhood from commodification arises because essential attributes are treated as severable fungible objects, and such treatment denies the integrity and uniqueness of the self. But if the social regime prohibits this kind of commodification, it denies women the choice to market their sexual or reproductive services, and given the current feminization of poverty and lack of avenues for free choice for women, this prohibition also poses a threat to the personhood of women. (1996, 127)

According to Radin's analysis, the commodification of women's sexual and reproductive activities creates a fundamental ethical problem; however, it is women's social vulnerability that nevertheless makes these markets essential to women's interests under certain circumstances. Thus, a woman's "personhood" is threatened in its integrity by markets in her sexual and reproductive labor but also threatened in practice by the social repression of such markets.

Regardless of whether we think there is a fundamental ethical problem with body commodification or with sex work, Radin's notion of the double bind helps to illuminate the situation that healthy volunteers face when they feel their integrity is undermined by clinical trial participation. Like the women Radin describes, healthy volunteers are also frequently socially vulnerable as racial and ethnic minorities who often lack preferable income

options. Furthermore, phase I clinical trials take place in confinement where participants are monitored and controlled in their eating, exercise, and even waste excretion, thereby experiencing what has been labeled a "temporal total institution" (Williams and Fisher 2018). Healthy volunteers, then, despite being majority male, are socially vulnerable in ways that might be comparable to some of the social vulnerabilities of women, including economic precarity but also submitting to the control of their bodies by others. In keeping with Radin's analysis, however, it is not obvious that the best thing for these volunteers is to disallow payment for their services; in fact, for some clinical trial participants, these payments offer their only way to make a living (Fisher 2013).

Phase I Participation as Employment?

Despite the reality that many healthy individuals participate serially in phase I trials as a means of earning an income, enrolling in clinical trials is not considered a form of employment. The money received is also explicitly not counted as a benefit of participation by ethics oversight boards tasked with determining that the risks of research participation are reasonable in light of the benefits of the research for the participant and society generally (US Food and Drug Administration 2018). The preferred narrative for accounting for incentive payments to participants, from an ethics oversight perspective, includes compensation for the healthy volunteer's time, inconvenience, and contribution (Grady 2001).

Because of how benefits are balanced against risks in justifying each clinical trial, it makes sense to limit how benefit is defined for oversight purposes. In short, if financial incentives were viewed as offsetting study risk, then even extreme health risks might seem justifiable if payments were high enough. However, the way in which risks and benefits of trials are balanced is an entirely different matter from whether payment for clinical trial participation is deemed a form of employment. It is compatible that payment for trial participation both is considered a form of employment and is not balanced as benefit against study risks.

How payments are categorized instead has much in common with the complexities of payment for other activities also deemed potential forms of body commodification. For example, similar to how healthy participants in clinical trials are paid "volunteers" so too are women who are paid for their oocytes considered "donors." Given that both phase I trial participants and women selling their oocytes are in fact largely motivated by financial gain, this rhetorical framing of each type of transaction seems warranted

only if some significant social and/or individual value is thereby preserved (Holland 2001). We remain neutral on substantive ethical questions regarding whether such values are thereby preserved and instead highlight here how payment labeling often reflects these values. Specifically, insofar as direct payment for the use of participants' bodies to study the effects of investigational drugs is considered inherently ethically problematic, we might thus presume the current narrative governing such payments aims to avoid these moral implications.

Yet, framing compensation as incentive rather than employment does not merely uphold the moral narrative of gratitude for volunteerism but, like the repression of markets in sex work and reproductive labor that Radin addresses for socially marginalized women, also has significant practical implications for phase I trial participants. That is because payment rhetorics that avoid body commodification have the double effect of also limiting participants' economic rights. In this way, healthy volunteers who do, in fact, participate in phase I trials as a means of earning a living do not have employment rights—rights that may give them more agency in setting the terms of their exchange with clinical trial sites as well as lessen their economic vulnerability. In other words, employment rights have the potential to curb the noxious effects of the very same commodifying markets in which healthy volunteers are engaged. In considering the ethical permissibility of markets in the body for biomedical development, then, we ought not be taken in so easily by a narrative deflection that avoids direct commodification. We should instead focus squarely on the question of what, if any, market norms will best protect the multiple ways in which healthy volunteers' welfare is wrapped up in clinical trial participation.

CONCLUSION

Commodification of the body raises ethical issues that have been widely explored in philosophy, especially in relationship to women's bodies. It may be that commodification is relatively avoided in the bioethics literature on payments to healthy volunteers because the population is largely male or because it is hard to get a grasp on what, if anything, is wrong with markets in the body. Some bioethicists also reason that since it is clear that participants must be paid as an incentive to volunteer, commodification offers an unhelpful moral complication (Stones and McMillan 2010; Różyńska 2018). Yet, if commodification of the body raises ethical problems, it does not follow that payment for healthy volunteers should be banned nor that such payments should be framed in ways that avoid those ethical problems.

In this paper, we have explored how phase I participants reflect on body commodification in clinical trials, putting these perspectives into conversation with philosophical and bioethical considerations. We have argued that participant perspectives on the sale or rent of their bodies in phase I clinical trials mirror the theoretical complexity and interpretive flexibility of body commodification while also shedding light on participants' own experiences in these trials. In particular, we have pointed out that when considering exploitation as an ethical harm of some forms of commodification, we need to address issues of relational equality and respect. Furthermore, we have explored the tie between gendered forms of body commodification and economic precarity as a means of understanding the "double bind" of body commodification in the context of largely male phase I clinical trial participation.

The ethical contours of commodification in phase I clinical trials are defined only partially by healthy volunteer perspectives. If body commodification is morally problematic, it may be so in ways that reach beyond the experiences of individual participants. Alternatively, healthy volunteers may have moral concerns about body commodification that are more reflective of social disapproval than of deep ethical problems with such practices. Talking to healthy volunteers directly about their perspective on whether they are involved in the sale or rent of their bodies is simply one avenue of interrogation that ought to be pursued on this topic. At the same time, this previously untraveled route has led to several significant insights regarding how participants in phase I trials view their inclusion in studies. These insights also hold potential for understanding the wider question of body commodification in clinical trials.

While different aspects of healthy volunteers' views about body commodification can be seen to support each of the surveyed philosophical contentions—from how body commodification is morally valenced to what solutions are reasonable in handling such markets—overall, we suggest a pragmatic approach that recognizes the double bind of participants who are both reliant on income from clinical trials and also vulnerable to the negative effects of such markets. This perspective suggests that an approach to such markets that also allows for employment as a clinical trial participant makes sense *if* doing so supports these individuals as agents able to more fully set the terms of their exchange with pharmaceutical companies and their associates. Determining how and whether such a reality could come to bear is beyond the scope of this paper; nevertheless, our argument shines light on how the conventional narrative of volunteerism

problematically obscures the market implications of payment for phase I participation.

ACKNOWLEDGMENTS

This work was supported by the National Institute of General Medical Sciences (NIGMS), U.S. National Institutes of Health (NIH) [grant number R01GM099952].

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