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FROM THE CHAIR

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In the spirit of pursuing controversial issues, our Committee’s panel at the Pacific Division meeting last April explored questions of justice and beneficence in drug trials. This edition of the Newsletter includes two papers from that panel: Ana Itlis, “Access to Investigational Drugs Outside of Clinical Trials,” and David Adams, “Investigational Drugs and the Desperately Ill.” Exploring the ethics of fertility, Bertha Manninen asks “What Did Octomom Do Wrong?”

This issue, like our previous one, contains two papers from the Society for Philosophy in the Contemporary World, which last year presented two sessions at the Eastern Division on “Health, Healthcare, and the Contemporary World”: Michael McClain’s “Strange Bedfellows: Ludwig Wittgenstein and the NIH on Pain,” and Jeremy Wisnewski’s “Perceiving Sympathetically: Moral Perception, Embodiment, and Medical Ethics.”

A paper delivered by David Ozar at the annual meeting of ASBH, “Attributing Agency to a Group,” and two book reviews, one of Mark Vicclair’s Conscientious Objection in Healthcare and one of Rebecca Skloot’s The Immortal Life of Henrietta Lacks (now in its eightieth week on the New York Times best seller list) complete the issue.

Contributions, letters, and suggestions welcomed.

Mary Rorty and Mark Sheldon

FROM THE CHAIR

The Committee on Philosophy and Medicine has been busy organizing sessions for each of the upcoming APA Divisional meetings. The panels are taking shape and each promises engaging presentations and lively discussions.

When the Eastern Division meets at the end of December in Atlanta, the Committee-sponsored session will address the issue of “Justice and Defining the Requirements for Health Care in a Decent Society.” This is a timely topic that will address issues at the heart of debates related to the Affordable Care Act that are likely to be the subject of lively political attention early in 2013. Committee member Leonard Kahn from the U.S. Air Force Academy will moderate the panel of six speakers—Marcus Arvan from the University of Tampa, Leonard Fleck from Michigan State University, Lily Frank from Queens College CUNY, J. Paul Kelleher of the University of Wisconsin, Stanford’s Govind Persad, and Amanda Favia from CUNY’s Macaulay Honors College.

In his presentation on a non-ideal theory of justice, Marcus Arvan from the University of Tampa proposes that a just minimum of health care should be determined through a quasi-democratic grass-roots process that respects the collective deliberations of the most disadvantaged. A decent health care minimum may be “different things in different places,” as determined by different human needs and values in different societies.

Leonard Fleck from Michigan State University is still trying to sort out which of two possible subjects he will present. One option will be to avoid the language of justice and formulate an argument in terms of “basic” or “essential” or “adequate” or “needed” health care services. His approach avoids the problem of choosing between competing conceptions of health care justice and embraces a contextual perspective that accepts as a fact that different conceptions of justice will be relevant and reasonable in different circumstances. His other option is a presentation on “Parsimonious Care: Does Ockham’s Laser Belong in Medicine’s Black Bag?” where he will defend the legitimacy of physicians’ role in rationing health care.

Lily Frank from Queens College, CUNY, plans to consider how the conception of “health” can be used to determine what is included in and excluded from the basic minimum of health care coverage. Using contraception as her primary example, she will demonstrate how the concept of health can be used to resolve allocation disputes.

J. Paul Kelleher from the University of Wisconsin will ground health-related duties in a more general duty of concern which is owed to others by virtue of their self-disciplined social cooperation under coercive institutions. Kelleher addresses Rawls’s idea of strains of commitment in explaining how some forms of classical liberalism demand health-related duties, and shows how his concern-based view explains widely held intuitions about when it is and is not permissible to aggregate smaller health benefits in preference to providing larger benefits to fewer people.

Govind Persad from Stanford University will discuss recent work in law and philosophy on the human right to health. By examining the implications of understanding the right to health care as a right to adequate or maximum care, he will argue that this right is best understood as a right to some form of adequacy.

Amanda Favia from Macaulay Honors College, CUNY, will focus primarily on Amartya Sen’s work on health equity and how it relates to defining a standard for universal access to health care, and will consider whether it is a public or private responsibility to provide the resources necessary for achieving this standard.

The Committee on Philosophy and Medicine will devote its session at the 2013 Central Division meeting in New Orleans to honoring Bernard Gert’s contribution to bioethics. Professor Gert died last December. He was a witty and generous friend and mentor who loved philosophy, teaching philosophy, and
Access to Experimental Interventions Outside of Clinical Trials

Ana S. Ilits
Wake Forest University

Should patients have access to experimental interventions outside of clinical trials? If so, when and why? Should physicians who want to provide at least some patients with experimental interventions be allowed or encouraged to do so even if there is limited evidence or there are ongoing trials? These and other related questions came to the nation's attention fairly recently through the Abigail Alliance litigation, and several decades before during the early days of HIV/AIDS treatment. However, not all cases in which questions regarding access to experimental interventions outside of clinical trials arise are like the situation that gave rise to the Abigail Alliance litigation.

This essay offers a framework for analyzing cases in which there is a patient (or parent) request for access to experimental interventions outside of clinical trials. The goal here is modest. I begin with the understanding that in bioethics (1) we often focus on cases as a starting point for identifying issues and drawing conclusions and (2) that casuistic reasoning plays a major role in bioethics education, in the bioethics literature, and in the way individuals and committees deliberate. If cases play this central role, then it is important to analyze and compare them carefully. This requires not only a normative framework for evaluating the question “What ought we to do?” but also a framework for ensuring that we accurately identify the facts of the case, understand precisely what is at stake in a case, and compare comparable cases. Treating disparate cases as if they were alike undermines the process of case-based discussions and reasoning. This essay develops a framework for analyzing the factual and conceptual aspects of cases involving access to experimental interventions outside of clinical trials so that we may deliberate about critical normative questions in an informed and systematic fashion.

Consider the following scenarios, all of which reflect efforts to obtain experimental interventions outside of clinical trials.

First is a fictionalized scenario based on a real study and the kinds of experience some parents of children diagnosed with cancer report. A randomized controlled trial (RCT) will compare standard treatment for children newly diagnosed with Ewing's Sarcoma (ES) to standard treatment plus another chemotherapeutic agent that is FDA approved and used for children with an ES recurrence. ES has a high recurrence rate, and the new regimen has been proven effective in putting children with a recurrence back into remission. This success is the impetus and justification for this study. The goal is to see whether the rate of recurrence can be reduced in newly diagnosed patients if the additional agent is added to the initial treatment regimen.

Jack is newly diagnosed with ES and his parents are told about the study. Jack’s parents ask his oncologist about trying the new regimen outside of the study. The standard therapy has a sufficiently poor success rate, i.e., there is such a high rate of recurrence in children using standard therapy, that they believe it is better for Jack to receive the experimental intervention and not be in the study, where he risks receiving the standard therapy. The oncologist informs them that since the experimental arm is experimental and has not yet been tested in newly diagnosed children, it is only offered in the context of a randomized controlled trial where half of the children will be randomly assigned to standard therapy and half to the experimental arm. They mention visiting another children’s hospital, and the oncologist informs them that no reputable pediatric oncologist at a reputable institution will treat Jack with the experimental intervention, even though all of the drugs are FDA approved and have been tested and used in children with ES.

The second scenario concerns the many cases involving women with metastatic breast cancer who sought to bypass studies of high dose chemotherapy combined with bone marrow transplants (BMT) and obtain the experimental...
intervention outside the studies. During the 1990s it was thought that this combination might improve outcomes for this group of women and clinical trials were initiated. Many women sought access to the experimental intervention outside of trials because they believed that the standard therapy arm of the studies offered unacceptable outcomes and it was worth trying the experimental procedures, which had been used successfully in patients with some other cancers. Initially third party payers refused coverage for what they deemed to be unproven treatment, but a series of lawsuits and threats of lawsuits changed the course and many insurers began covering the high dose chemotherapy and BMT protocol. The trials eventually were completed far behind schedule because of slow enrollment and the experimental arm had worse outcomes than the standard therapy.4

Third, consider studies of PLX4032 for the treatment of melanoma. A September 2010 New York Times article tells the story of two cousins, both in their 20s and diagnosed with melanoma around the same time, who enrolled in a RCT for PLX4032 (Harmon 2010). The first cousin to enroll in the trial was assigned to the experimental arm and initially responded well to treatment. When the second cousin enrolled, he was adamant that he receive PLX4032. His oncologist apologized and said he had been randomly assigned to the standard therapy arm and that there was nothing he could do. Moreover, he informed the young man and his mother that no other cancer center would re-screen him and enroll him in the trial, a move they thought might give him a chance of being assigned to the experimental arm to which he desperately wanted access. PLX4032 was not FDA approved and no one would give it to him outside of a trial, so the only way to get the drug was to participate in the study and get assigned to the experimental arm. The young man randomized to the standard therapy arm died within a year. The cousin assigned to the experimental arm outlived his cousin, although the drug did not provide a cure. The drug has since been approved by the FDA and shown to increase median survival of patients with some types of melanoma (Genentech 2011; Flaherty 2010).

These scenarios all involve access to experimental interventions outside of clinical trials, yet there are important differences among them. This paper identifies key terms and distinctions relevant to evaluating requests for access to experimental interventions outside of clinical trials and proposes a framework for analyzing and comparing cases.

**Key Terms: Access, Experimental Intervention, and Clinical Trial**

To explore the ethical issues regarding access to experimental interventions outside of clinical trials, we must be clear about what problem or purported problem we are exploring. Clarity about the words we use to describe a situation is important; in particular, we must know what we mean by “access,” “experimental intervention,” and “clinical trial.”

Access. In each of the scenarios above, “access” refers to something different. In the Ewing’s Sarcoma case, the oncologist explained that even though the experimental agent was FDA approved and available, no reputable pediatric oncologist would provide it. Access referred to physician willingness to prescribe a legally available medication. In the breast cancer studies, access turned primarily on whether or not third party payers would cover the costs of the expensive interventions. Although some oncologists were concerned about offering the treatment outside of a trial, many were willing to do so or even felt an obligation to do so (see Mello 2001). The key issue for many women seeking the experimental intervention and physicians willing to provide it was coverage. In the melanoma case, the access issue was primarily one of a lack of FDA approval and secondarily one of research centers agreeing not to allow people to attempt to re-enroll in a trial so as to be assigned to a different arm than the one to which they were originally assigned. Access turned on getting into the “right” study arm, and there was only one chance to “flip the coin.” In other cases, access might depend on a pharmaceutical company’s willingness to release a drug for use and FDA permission to release such drugs. This was one of the issues that emerged in the Kianna Karnes case. Karnes was a 44-year-old dying of kidney cancer who wanted access to two experimental drugs through “compassionate use” exemptions. The drug companies chose not to release the drugs even though they had FDA’s permission to do so (Annas 2007). Access referred to the willingness of a pharmaceutical company to sell or give access to a product the FDA allowed them to offer an individual or group (Groopman 2006). A further distinction sometimes relevant to the discussion of access is whether we mean access in a convenient location relatively close to home or access anywhere. For example, if someone wants a drug that has not been approved in the U.S. but the drug is available in Mexico, should we hold that patients in some sense have access to it?5 Barriers to such access may include FDA policies, pharmaceutical companies, physicians acting in their capacities as clinicians or researchers, third party payers and money, or a combination of geography and convenience.

Experimental. In the scenarios above, the features that rendered an intervention experimental varied. In the ES case, the drug was FDA approved and already in use for children with a recurrence of the same cancer being studied. The experimental piece was using it in newly diagnosed children. In the breast cancer studies, high dose chemotherapy and BMT were standard treatments for some other cancers, but they were experimental for metastatic breast cancer. In the melanoma case, the drug being studied was not FDA approved. One can imagine an alternative scenario in which a drug is not FDA approved and is being studied in the U.S. but is approved in another country. Those are very different senses of “experimental,” and one can imagine patients and clinicians who might argue for access to some kinds of experimental interventions and not others.

Clinical Trial. The scenarios above all involved randomized controlled trials where the control arm would receive standard of care. The term “clinical trial” could refer to other study designs, such as placebo controlled trials in which some participants receive an inactive intervention or an observational study in which people are monitored and data collected but there is no randomization to different interventions. In some cases, the types of clinical trials for which a particular person is eligible may influence our judgments about whether or not it is problematic to deny access to an experimental intervention outside of a study. For example, if there is significant reason to study the safety and efficacy of a drug on an ongoing basis but a trial is designed in such a way that it is open label and people choose their study arm, then someone who defends outside access might be less inclined to say that someone who is eligible for a study still should have access outside the trial. We might also think about cross-over studies in which all participants are randomized to each study arm at some point during the trial differently than how we think about standard randomized controlled trials. In discussing the ethical issues associated with access to experimental interventions outside of clinical trials (or the lack of access), it will be important to know what we mean by “clinical trial.”

**A Framework for Analysis**

With these distinctions in mind, we are left to ask: When (if ever) is it permissible to allow patients to access experimental
interventions outside of a clinical trial? When (if ever) is there an obligation to offer such access? (An additional question is: Who bears such an obligation?) There are a number of considerations that are relevant to analyzing and answering these questions, and understanding these can help us make judgments and distinguish among different types of cases. We can think of some of these considerations as axes. Each axis reflects a spectrum of possible considerations. Part of making judgments is determining the facts of a given case. Not all of these axes will be relevant to all cases or questions of access to experimental interventions outside of clinical trials, because not all cases are alike.

- **Seriousness of the condition**: The range here might go from something many would not consider a “condition” at all, such as a desire for longer eyelashes, to what many would recognize as a mild condition to a seriously disabling condition to a fatal condition.6

- **Existence of safe and effective standard treatments**: Key points on this axis include cases in which safe and effective treatments are available, cases in which effective treatments exist but they have modest safety profiles, cases in which treatments impose a high degree of risk or burden, and cases in which nothing known to be even moderately safe and effective currently exists.

- **Accessibility/availability of safe and effective standard treatment**: The range extends from treatments that are readily available and accessible, to cases where the treatments that exist are highly inaccessible or scarce (e.g., heart transplants).

- **Regulatory status of the experimental intervention**: An experimental intervention may be legally accessible (approved and could be offered if willing), to available only through compassionate use or other special routes, to not approved in U.S., to not approved anywhere in the world.

- **Third party payer coverage status of experimental intervention**: Key points on this axis range from interventions that are covered by most third party payers for people with this condition, to interventions covered by only some third party payers for this or another condition, to interventions covered only with a fight, and, finally, to those not covered at all.

- **Degree or level of constraint**: In some cases there may be no constraint on access. In others there will be moderate constraints, and in yet others there may be significant constraints. As noted earlier, the nature of the constraints can vary, including regulatory, corporate, physician, third party payer, or other financial constraints.

- **How much and what kind of evidence exists favoring the experimental intervention**: Evidence in support of the safety and efficacy of an experimental intervention may be lacking altogether, there may be moderate evidence in support of it, or there may be a high level of evidence to suggest that the intervention is safe and effective. It is important to note here that there is an extensive literature about what constitutes such evidence in the philosophy of medicine (see, for example, Gerber et al. 2007; Sargent 2010; Allmark 2004; Ashcroft 2004; Worrall 2007).

- **What level of evidence is necessary or appropriate for choosing an action**: When individuals have a rapidly advancing life-threatening condition, the level and quality of evidence they require regarding a drug’s safety and efficacy may be lower than that required by a healthy person seeking a preventative intervention. We can imagine numerous points on the spectrum between those two extremes.

- **The potential benefits the experimental intervention might offer**: The quality and magnitude of possible benefits may be a relevant consideration. Potential benefits may include improved safety, efficacy, convenience, and cost, and the scale may be from minimal to great.

- **Risks associated with the experimental intervention**: The magnitude and nature of the risks associated with experimental interventions range from unlikely to occur to highly like to occur. The quality of these risks range from minimal (e.g., mild, temporary itching) to significant (e.g., death or permanent disability).

- **Relationship between patient and physician and the obligations physician-investigators have**: The research ethics literature is replete with arguments regarding the dual role of clinician-researchers. The range of views extends from arguments defending the view that clinicians have fiduciary obligations that cannot be abandoned in the research setting, to the view that investigators have radically different roles and do not have fiduciary responsibilities toward research participants. (For further discussion see, for example, Miller and Weijer 2006; Litton and Miller 2010; Miller and Brody 2003; Morreim 2005.)

- **The quality and magnitude of different interests that are at stake in a given case**: A number of possibly competing interests may be involved. Interests may include:

  - Public interests, such as ensuring safety; protecting people; promoting long term health; and advances in medicine.

  - Corporate interest, such as acquiring data, securing approval, and being able to sell a good product for a profit.

  - Individual interests, such as self-preservation and privacy.

  - Physician-investigator interests, such as caring for patients and being seen as successful researchers.

  - Physicians who are not researchers: knowing what is most likely to be best for their patients and being able to offer their patients what they think is in their best interest.

The magnitude of the interest may range from cases in which access decisions have no effect on a particular interest to having a very significant effect on the interest.

It is important for any given discussion of access to experimental interventions outside of clinical trials to determine which axes are relevant to the case and then to identify the facts of a particular case with respect to the relevant axes. The axes and factors here are data points of a sort to help us identify what should be considered in making judgments so that judgments are grounded in facts and in careful analysis of the case. That doesn’t mean, of course, that judgments are necessarily uniform. Different judgments will reflect different values, priority tradeoffs, and background assumptions. Making a judgment about who should be willing to prescribe is different from who should be willing to sell/give away a product and that is different from the question of...
who should be willing to pay for it. We must be clear in our analyses about what specific actions are being requested, on whom some seek to impose obligations, etc. In analyzing cases we should be careful to specify precisely what decision or decisions are to be made.

Applying the Framework to Analyze and Compare Cases

The remainder of this essay uses the distinctions regarding key terms and the axes described above to compare the fictional ES and melanoma cases described earlier. The term “clinical trial” is used in a similar way in both cases; it refers to a randomized controlled trial in which some participants receive the current standard of care and others receive the test intervention. The term “experimental,” on the other hand, is used differently. In the ES case, the test intervention consists of approved drugs that have been studied in children with a recurrence of the same disease. The experimental element is using the drug combination in newly diagnosed children. In the melanoma case, the test intervention is in the early stages of human testing and is not FDA approved. The cases involve two different kinds of barriers. In the ES case, the barrier was physician willingness to prescribe. The drug was approved and available, and third party payers probably would have covered it. In the melanoma case, the test intervention was not approved and not available to anyone outside of researchers. A physician could not legally choose to provide it outside the trial.

With respect to the various axes most relevant to these cases, we see some similarities and many differences. Key similarities are that both conditions are serious and in both cases patients have a significant personal interest, physician-researchers have interests, as do society and corporate stakeholders. These interests differ, though, in that in the ES case, all of the drugs are already approved and on the market, so there is no corporate interest in the FDA approval process itself. A major difference is that although the standard of care is not perfect for either condition, the standard of care for ES has a far higher success rate than that for melanoma. There were also significant differences between the ES and melanoma experimental interventions in terms of regulatory status, third party payer coverage, evidence supporting the intervention’s safety and efficacy, and its availability on the market. Physicians had far more safety data for the former, the risks of the intervention had been studied in a similar population, and the intervention had FDA approval. This was not the case for the melanoma test intervention. Given the coverage for cancer therapy, it is likely that a third party payer would have found coverage for the ES drug reasonable given that the drug had been studied in a recurrence of the same cancer. The melanoma intervention was not available for sale and hence not eligible for coverage. For those who hold that physicians have strong fiduciary duties that cannot be abandoned by asking patients to enroll in a clinical trial, these cases might look quite different. In the melanoma case, the physician researchers might be willing to prescribe off label if they think it is the best decision for a patient, but they are not allowed to do so. In the ES case, even though it might be reasonable for a clinician to judge that it would be appropriate to treat a child newly diagnosed with ES with the experimental intervention, since it has been shown to be safe and effective in children with an ES recurrence, here the clinician-investigators refused to do so because they wanted to be able to collect data, complete the study, and answer an important question. It would be reasonable to think that a clinician with knowledge of the studies demonstrating the efficacy of the ES test intervention in children with a recurrence of ES might be willing, or even anxious, to prescribe it to newly diagnosed children. In the world of adult oncology, we would expect that if there were good evidence that a combination of approved drugs could be used to treat a newly diagnosed patient, a physician would be willing to provide the intervention outside of a study (Shilsky 2011; see also Menikoff 2006, pp. 240-41). Moreover, if there were no current trial comparing the experimental intervention to the standard of care for newly diagnosed ES, we would not be surprised to see pediatric oncologists using the experimental combination in such patients. However, given that there is a trial, there is a strong interest in providing the intervention only in the trial. In the melanoma case, physicians simply would not have had access to the test intervention, but had they found a way to access it, it is reasonable to think that some would have prescribed it because the patients in question had a very serious, life-threatening illness. Individuals who hold that clinician-investigators have radically different obligations from clinicians and do not have fiduciary obligations to do what they think is most likely to advance a particular patient’s interests might not worry about these issues.

Given the variety of differences, one could argue that access in the ES case should be granted while in the melanoma case the physician-investigators do not have this obligation. (Whether the FDA and pharmaceutical companies involved have obligations with respect to providing access is a separate question.) One might not come to that conclusion and instead hold that restricting access in both scenarios is permissible or that in both cases the patients should have access outside of the studies. But the cases are different and justifications for requiring access or restricting access will have to attend to different issues.

Cases like these concerning access to experimental interventions outside of clinical trials may elicit gut reactions that sometimes are very strong, particularly when the conditions patient-participants have are serious. The NY Times article generated extensive discussion in the days and weeks following its publication. This essay has demonstrated some of the nuances relevant to discuss such cases, highlighting some of the ways in which an examination of various axes can help us analyze and compare cases systematically. A framework for analysis does not in itself yield normative judgments, but it shapes the character of our evaluation in a way that is important if we value coherence and fairness (treating like cases alike).

Endnotes

1. For a summary of the issues and outcomes in the Abigail Alliance litigation, see Jacobson and Parmet 2007 and Leonard 2009. For a discussion of the debate surrounding access outside of trials and accelerated access to new interventions in the context of HIV/AIDS, see Salbu 1994 and Epstein 1996.
3. For further discussion of the clinical trial on which this case is based, see Holcombe et al. 2003; and Menikoff, 2006, pp. 244-47. Note that this is a fictional account and does not reflect anything that I know to have happened in that case.
4. For further discussion, see Mello 2001. See also Menikoff 2006, pp. 124-29.
5. The suggestion that patients might access experimental interventions by traveling to other countries raises the many issues associated with medical tourism, including concerns about safety and quality. For further discussion of medical tourism, see Alleran 2010; Cohen 2012; York 2008.
6. It is important to recognize here that there is an extensive literature concerning the classification of disease and not all will agree on what counts as a disease or condition and, if so, how to rate the disease or condition. For further discussion of the classification of disease, see Margolis 1976 and Engelhardt 1976.
Two features of these types of cases are salient: (1) the type of access demanded and (2) the reasons given for demanding it. As to the first, I will say that persons like Jones demand direct access to a drug in that they insist upon receiving an unproven therapy in the form of an investigational new drug (IND) at a point in its development no later than the conclusion of Phase I trials, and without being enrolled in any phase of a study aimed at determining the safety or efficacy of the purported treatment represents for them a “last chance” effort to obtain a cure—that is, the individuals cannot wait until the standard of practice for their type of cancer (e.g., chemotherapy regimens, radiation, surgery, endocrine therapy), but the rapid rate of solid tumor growth is not decreased. Convinced Jones has only months to live, her physician recommends hospice care. Though she is now too ill to meet the eligibility criteria for ongoing clinical trials dealing with her type of cancer, Jones hears rumors of an as-yet-unproven treatment—an investigational new drug (call it ‘D’) targeting fast-growing tumors that is just completing Phase 1 safety testing. Believing she lacks other viable options, Jones regards this novel oncologic agent as a “last chance” therapy. “I’m desperate,” she says, “I’ll try anything. It’s my only hope.” Jones insists upon a right to access D directly, outside of and prior to the completion of research trials.

How should we respond to such a demand?


approval process is completed to obtain the drug and will not have enough time to try any other INDs before the harm in question befalls them.2

Should we satisfy Jones’s demand and grant direct access to the desperately ill? I want to explore one kind of reason we might have for refusing to meet Jones’s demand or to endorse policies that would allow such demands to be met: namely, we should not allow persons to obtain direct access to INDs when they are under an obligation not to do so. Persons like Jones, I will suggest, have a pro tanto obligation to forgo direct access to INDs. To ground this claim, I will develop a line of argument occasionally suggested in the literature,3 though not systematically argued—namely, that those who benefit from the enterprise of investigational research incur some obligation to support it, rooted in what John Rawls called the “principle of fairness.” Having made that case, I will take up and try to respond to several objections. First, however, some brief background.

Since the 1990s, “expanded access” regulations have permitted small numbers of patients to obtain potentially life-saving drugs for treatment purposes more quickly than they otherwise would and before all testing has been completed. The latest regulations generally bar access to any IND prior to Phase 2 testing. Widespread access for a large population is permitted only when providing the IND will not interfere with ongoing clinical investigations of the drug that could support marketing approval. Additionally, the sponsor (often a pharmaceutical manufacturer) must agree to provide the drug but cannot be compelled to do so.5 Sponsors may recover only “the direct costs of making [the] investigational drug available,” and only if there is “reasonable assurance that charging will not interfere with developing the drug for marketing approval.”6

In 2003, an organization founded by the family of Abigail Burroughs, who died at age twenty-one of metastatic skin cancer, sued the FDA to overturn its policy barring direct access to post-Phase 1 INDs. The litigation followed submission of a joint Citizen Petition to the agency by the Alliance and the Washington Legal Foundation, asking the agency to permit commercial sale of any IND to persons with an “immediately life-threatening disease.”7 The petition was rejected; but in a subsequent legal action by the petitioners a panel of the D.C. Circuit Court (in a ruling later overturned) agreed with the family, holding that terminally ill persons have a “fundamental right” to obtain “potentially life-saving” post-Phase 1 drugs.

The demand for direct access made in Abigail Alliance was a claim for something not permitted under any existing regulations; desperately ill persons like Jones should be allowed to obtain, through sale, any IND that has completed Phase 1 study.8 The Alliance’s arguments for this claim are inadequate, as I will try to show shortly; I want first, though, to examine whether individuals like Abigail Burroughs or Jones might have moral reason to forgo direct, off-trial access to INDs. I will suggest that they do.

II

According to the principle of fairness, there are certain conditions under which one can become morally bound or obligated to act or refrain from acting in certain ways without having tried to bring about that result. As Rawls explains, the principle of fairness—or “fair play”—depends upon the existence of “a mutually beneficial . . . scheme of social cooperation” the advantages of which “can only be obtained if everyone, or nearly everyone, cooperates.” This cooperation “requires a certain sacrifice from each person, or at least involves a certain restriction of his liberty.” Under these conditions, Rawls says, “a person who has accepted the benefits of the scheme is bound by an obligation of fair play to do his part and not take advantage of the free benefit by not cooperating.”9 The following kind of case seems to capture what Rawls and other defenders of the principle of fairness have in mind.

Smith’s neighbors come together to clean up and beautify a neighborhood park. They each pledge monthly contributions of money to create a fund for purchase of the needed equipment and set up a schedule when each agrees to donate time working at the site. They adhere to these rules and restrictions, with the result that everyone in the neighborhood, regardless of whether they cooperated to improve what had been an eyesore, may now enjoy a beautiful spot for relaxation. Smith loves the outdoors and relaxing in it. He is delighted that others have cooperated to refurbish the park. He desires to use it and goes out of his way to do so, re-arranging his work hours and vacation just so that he can spend mornings strolling through the greenery. He acts to obtain maximum advantage from the park’s new availability. He understands that the park didn’t regenerate on its own; rather, he realizes that others (his neighbors) sacrificed to make the benefits he now enjoys possible, and he is happy to obtain for free something he prizes highly, regardless of its cost to others. His neighbors approach Smith and ask for a “fair share” contribution to the fund for ongoing park maintenance. He is easily able to comply.

Surely Smith is liable to face widespread censure if he refuses. The best explanation for the reaction Smith encounters is that he has incurred, by virtue of his desires, intentions, and conduct, a pro tanto obligation to play by the rules and pay his fair share to support the park.

The conclusion that Smith has acquired an obligation of fair play here has seemed intuitively plausible to many, though complete agreement on why this is so remains unsettled. I will not pursue that question here, but simply assume that many people share similar reactions to cases like Smith’s. My overall aim is to show that investigational research is a cooperative enterprise from which Jones has benefitted in just the way that Smith benefits from the efforts of his neighbors, and (consequently) that Jones has a pro tanto obligation of fair play just as does Smith—that is, she has good, though overridable, moral reasons for thinking that she should do her fair share with respect to supporting the cooperative scheme of clinical research.

The principle of fairness has generated a large literature, and since there is no time here to canvass the familiar moves in the discussion over how to delineate the fair play principle, I will simply set out a plausible list of conditions emerging as I see it from that literature.10 To that end, I will start with this set of conditions:

A person, P, is bound by an obligation of fair play only if:

1. There is a cooperative enterprise made possible by the willingness of others to restrict their liberty in certain ways;
2. The cooperative enterprise produces non-excludable goods—that is, goods from the enjoyment of which no one can be left out, since once they are made available to some, they are enjoyable by everyone;
3. P is a beneficiary of the enterprise in that he enjoys a share of those goods;
4. P has accepted the goods in question qua benefits of the enterprise; and
My claim is that Jones’s case satisfies these conditions. Let me outline briefly how the argument for that claim might go.12

To begin then, it seems plausible to say that the system of investigational research satisfies the first two conditions, in that it constitutes an ongoing cooperative venture, sustained by the willingness of research participants to make certain sacrifices in order to create new drugs and the opportunities to use them. Moreover, the opportunities produced by the enterprise of investigational research appear to be non-excludable, since their availability does not depend upon having cooperated in their creation. Jones is plainly a beneficiary of that cooperative scheme; and she is not a mere unwilling recipient of benefits for which she neither asked nor cared to receive. Rather, she actively sought to obtain those goods. Several points should be made here. First and ex hypothesi, Jones has already consented to and accepted medical treatments and procedures for her cancer that were themselves almost certainly made possible only through the cooperation and sacrifice of others in previous studies. Second, Jones has gone out of her way to obtain exactly those benefits the enterprise of investigational research has to offer. To see the significance of this fact, recall that Jones demands direct access to a particular drug, D. We might naturally wonder why she has singled out D in this way. But it is more revealing to ask why she insists on access to any IND whatever. After all, the domain of unproven, purported therapies for disorders like cancer includes not only those agents or procedures not yet shown to be effective, but also those not shown to be ineffective. That domain is extensive, if we take it to include therapies available through sources of alternative or unconventional medicine. Typically accessible without restrictions, these therapies are routinely used by a significant number of cancer patients annually13 and include homeopathic and naturopathic treatments; macrobiotic, high-fiber, oxidative, and calorically-restricted diets; dietary supplementation with megavitamins and herbal products; metabolic treatments; enemas to “detoxify” and cleanse the body; use of bioelectromagnetics and immunoaugmentative regimens.14 While a few are reported to have been disproven, most have not been subjected to rigorous testing.15 Not surprisingly, many such alternative therapies are almost entirely supported by testimonial evidence in the form of reports of isolated cases, the credibility of which is difficult to weigh.16 Jones might reasonably believe such evidence cannot function as a reliable indicator of truth—such data are not sufficient warrant from which to draw general conclusions about the causal properties of particular substances.

The point, of course, is that despite her desperation Jones doesn’t want access to just anything purporting to be therapeutic. She is not epistemically ecumenical in this way; rather, she seeks direct access to investigational therapies for which there is at least some preliminary evidence of the sort supplied by familiar aspects of basic science (cell line studies, animal testing, other forms of lab data, etc.). Finally, Jones has not only sought and accepted the fruits of clinical investigation, she has accepted them as benefits. We can reasonably attribute to her the belief that the course of her medical treatment thus far has included drugs approved for use in treating her disease made possible only because others undertook the burdens of enrolling in previous trials. For these reasons, Jones’s case appears to fulfill conditions 3 and 4.

Jones’s case also satisfies condition 5. Her demand for direct access constitutes a refusal to play her part as defined by the rules of investigational research. Yet by refusing to do her part, Jones threatens to harm that system. We can best see this by asking what reasons she might give for skirting compliance with the constraints on research. Jones has only two such relevant reasons: that she is desperately ill and that she has a terminal condition. (These are not coextensive, of course.) Neither reason is sufficient to justify a claim of direct access: For each would permit such widespread off-trial use that the cooperative system of investigational research may no longer be stable or viable, at least for important subsets of patients with morbid or fatal conditions. Take first the fact of being desperately ill. Jones is threatened with the irreparable harm of death from cancer. Cancer, of course, is not the only deadly disease and (more to the point) death is not the only irreparable harm such that the desire to avoid it, together with the lack of any remaining options, could make someone desperate. Consider, for example, patients facing the imminent loss of limbs due to worsening peripheral vascular disease, the approach of renal failure brought on by malignant hypertension, the inevitable cognitive devastation of early-onset Alzheimer’s, or impending blindness due to macular degeneration. Each of these individuals (and many more could easily be imagined) confronts an impending and irreparable harm of serious injury or profound disablement. We can further suppose each has exhausted all conventional, approved treatments for his or her malady, and that each now seeks direct access to what he or she considers a “last chance” therapy: no other options remain before the harm with which each is threatened befalls him.

If the fact of being desperately ill entitles Jones to direct access then it is hard to see how each of the above patients would not have an equally strong claim to the same. This result reflects tremendous moral pressure to expand the categories of persons to whom such access must be given. Such an expansion threatens to unravel the on-going cooperation necessary to sustain clinical research. No desperately ill person can be assured of meeting the eligibility requirements of a study testing their last chance drug, and we cannot reasonably expect them to remain in a trial if they come to believe they are in the control arm and have the “out” of direct access. Direct access is guaranteed access, and this fact is a powerful reason to defect and refuse research participation.

To this argument, advocates of direct access may point out that Jones is desperately ill with a terminal condition, and only when the irreparable harm with which one is confronted is death does one have a claim of direct access. But this restriction is difficult to motivate, since there does not appear to be a non-arbitrary way to pick out a class of relevantly “terminal” individuals. Imagine three patients all newly diagnosed with cancer. A is told that unless her disease responds to standard treatments such that it will likely kill them is desperately and
terminally ill and thus may defect from the cooperative scheme of research to obtain direct access, then the continuing viability of investigative research on anyone with such conditions is threatened. As this is an outcome we should resist, the claim that harm to the system of research is avoided when direct access is given only to the terminally ill is not defensible.

If I am right in all this, then each of the conditions I began by listing as necessary for a fair play obligation appears to be satisfied in the case of the desperately ill. Let’s assume, then, that persons like Jones incur a pro tanto obligation with respect to investigational research. In what exactly does this obligation consist? Rawls answers that one must do his or her “fair share” to shoulder the burdens or costs associated with maintaining the cooperative scheme.17 As applied to Jones, this suggests a two-part obligation: (1) to become a research participant herself and, more generally, (2) to play by the rules of the cooperative enterprise. About the first obligation I will have nothing more to say here,18 for the second is the more immediately fundamental and relevant obligation.

As Rawls and others make clear, the essential feature of a fair play obligation is to “do [one’s] part as defined by the rules,” as compliance with them is necessary to sustain a viable practice.19 In the case of research, Jones can fairly be asked to shoulder those burdens shared by all who cooperate to make research possible by structuring trials in a way aimed at producing valuable results even though this means putting up with a variety of burdensome restrictions: strict exclusion criteria; “wash-out” periods; double-blinding; placebo arms; restrictions on dosing and concomitant therapies; lengthy follow-ups; draws, punctures, biopsies, and other invasive procedures; and long delays before final approval. Since a fundamental rule of the research enterprise says that to obtain access to a drug like D one must enroll in study, Jones appears bound to abide by it.

III

It remains then to consider whether an obligation to comply with the rules of the research enterprise might be objected to as overridden by countervailing reasons of a more weighty sort. At least two such reasons were offered in the Abigail Alliance case. The Circuit Court panel articulated the first: A desperately ill individual may invoke and permissibly exercise a right to defend herself.20 Customarily the right to use defensive force is conceived as a permission to use reasonable force to repel an unlawful aggressor.21 The claim is that this applies to the desperately ill, who (in the words of one legal scholar) have a right of “medical self-defense.”22 Since Jones is under attack, she may defend herself even if in doing so she violates her obligation. Let’s call this the “defensive-force argument.”

The analogy at the root of the defensive force argument is so attenuated that it cannot gain useful moral traction: While in some sense it is true that Jones is seeking to repel a deadly threat, it is not so difficult to think of a cancerous tumor as an aggressor in the way the law contemplates. At common law, defensive force may only be deployed when the attacker’s use of force is unlawful. Obviously, cancer is not a moral agent and neither behaves lawfully nor unlawfully in the relevant way. Moreover, under the standard view a victim cannot deploy deadly force to repel an attacker unless death is imminent. But it is counter-intuitive to insist that Jones must wait until her disease is about to finish her off before she can “fight back” (with cancer-killing drugs, radiation, and so forth). Lastly, even if we agree that “people should generally be free to defend themselves against that which is threatening their lives,”23 nothing immediately follows about what persons may lay claim to in order to accomplish that purpose. For all of these reasons, the defensive-force argument must be rejected.

A second countervailing reason suggested by the Court involves the idea that it is permissible to do what is necessary to save one’s life in a circumstance of extremity. The Circuit Court puts it this way: The desperately ill have a “right of self-preservation” permitting “persons in mortal peril . . . to try to save their own lives, even if the chosen means would otherwise be illegal or involve enormous risks.”24 The thought here involves what in law has been called the defense of necessity. The claim is that an actor is justified in committing what would otherwise be a violation of the rules if he is unavoidably and through no fault of his own confronted with an imminent danger such that violating the law is not just a means of averting the harm but also the only means of doing so.25 The desperately ill are justified in violating their obligation to support investigational research so as to avert the irreparable harm looming over them. Call this the “necessity argument.”

The necessity argument won’t work. In the familiar case, if you are trapped on a mountain by a storm and breaking into my unoccupied cabin is the only means of survival, you are permitted to do so. Yet this is because there is (we assume) obvious evidence that violating the rules of property in this circumstance will have—and is the only means to obtain—the desired effect: shelter from harm. By contrast, even if you sincerely believe that breaking into my cabin will cure your cancer, the absence of evidence demonstrating a causal connection means that violating the rules of property in that case is not justified.26 The problem for Jones is clear: Evidence that violating the rules of clinical trials (by obtaining direct access to an IND) is a necessary means of avoiding a threatened harm (of serious injury, disablement, or death) is just what the desperately ill do not have. Jones may believe the proposition “Directly accessing D will prolong my life” (i.e., the level of her evidence for it) must be very low. This is because a demand for direct access effectively short-circuits the acquisition of the very evidence the desperately ill need to make a claim of necessity credible. Uncontrolled Phase 1 trials often enroll very small numbers of patients from which almost no useful data concerning comparative effectiveness may be derived. Moreover, the predictive value of Phase 1 trials is notoriously poor: Only about 10 percent of patients enrolled in Phase 1 oncology trials respond positively to the therapies they obtain27 and only a small percentage of INDs undergoing Phase 1 investigation go on to be approved.28 Jones cannot claim that D is necessary to her survival, for she has as yet no significant evidence of the sort her own epistemic standards require showing that D will have any beneficial effects whatever, let alone that it will save her life. And if the drug can’t be shown to be necessary for her survival, neither can be the opportunity to obtain it. Hence, the necessity argument should also be rejected.

IV

I have argued that we should not permit the kind of access to INDs demanded by the Abigail Alliance. Legislation recently proposed in Congress and premised on the Alliance’s claims should also be rejected. The ACCESS Act would permit “seriously ill” persons who “face morbidity” and have exhausted all approved treatments to access INDs directly as long as the potential risk to a patient of the condition or disease outweighs the potential risk of the product, and the product may possibly provide benefit to the patient.29 This language goes too far. Nearly everyone with a serious medical problem faces some eventual morbidity, and even for Phase 1 drugs with only a remote chance of being approved it is still possible that they may cause a positive response. The bill’s language thus would permit vast numbers of the sick to acquire any IND they can afford to
buy regardless of how ill-supported by meaningful evidence or how potentially dangerous—subject only to the constraint that the drug won’t kill the user faster than their disease would (the limiting case of a favorable risk/benefit ratio). This proposal has therefore all of the problems I have outlined for what I call “direct access” and should be opposed for that reason.

A concluding observation. I suspect my argument is likely to leave us with a somewhat bad moral taste in our mouths. There seems to be something churlish and uncaring about responding to the entreaties of the desperate by reminding them that they are obligated to give up their one last chance (as they see it) to live. And surely it would be, were this all we could do for them. Abigail Burrough’s family blamed the FDA because they believed (probably falsely, as it turns out) that the IND she sought would have saved her life. Petitions, court documents, and other material produced by the Alliance made repeated assertions of the following sort: “Abigail might well have been saved by faster FDA action”30; Abigail’s doctors knew there was “a significant chance of saving her life” if she could be given the drugs she sought31; the denial of direct access meant, said Abigail’s father, that “we could not keep Abigail alive.”32 Yet, eight years after Burroughs’s death, the Journal of the National Cancer Institute concluded that studies conducted on Cetuximab (also known as Erbitux, one of the tumor-fighting drugs Burroughs sought) showed the drug on average extended the life of some cancer patients by as little as five weeks.33 The comments of the Alliance reflected the expectation that direct access to INDs would have brought about significant changes in the prospects for Abigail and other desperately ill persons who were denied them. But (and as I have tried to show) the very nature of direct access generally precludes reliance upon the sorts of evidence needed to warrant such expectations.

The desperately ill face loss for which cure or disease-free remission are too often not realistic goals. We therefore owe it to persons like Abigail Burroughs and Jones not simply to instruct them on their (and our) obligation to support ongoing medical research, we must also work to create those conditions instruct them on their (and our) obligation to support ongoing medical research, we must also work to create those conditions in which they will enable them to formulate and bring to bear a different set of expectations for dealing with irreparable loss of functionality or of life. How exactly to do that, however, is a topic for another time.34

Endnotes

1. There are some cases where we may not be sure whether a treatment is investigational or standard. But I will set that worry aside here.
2. For the sake of simplicity, I will confine claims for “direct access” to INDs, though there is no reason why medical devices and procedures could not also be the subjects of claims for direct access.
8. Arguments for this claim are made, e.g., in Volokh 2007; Currie 2007; Plonias 2008; McNamara 2010; Cerino 2008. See also Schuklenk and Hogan 1996 which, while not arguing for direct access, makes a case that a subset of the desperately ill—terminally ill patients—have a right to violate the rules of investigational research. I take this up later.
10. I review the standard moves in a longer paper from which this article is drawn.
11. The term is Klosko’s. See Klosko 2004.
12. Much of what follows is abbreviated from a longer version of this paper.
17. See Rawls 1971, p. 112; Klosko 2004, p. 34. See also Carr 2002, p. 11.
18. Naturally there is much that could be said, some of which I take up in the longer version of this paper.
19. Rawls 1971, p. 111. H.L.A. Hart says much the same: “When a number of persons conduct any joint enterprise according to rules and thus restrict their liberty, those who have submitted to these restrictions when required have a right to a similar submission from those who have benefited by their submission.” Hart 1955, p. 185.
21. See Dressler 2009, pp. 223-34.
23. Ibid., p. 1826.
24. 495 F.3d 695 (2007), p. 23. The proposed “ACCESS” Act makes the same appeal: “Seriously ill patients have a right to take actions to preserve their life by accessing available investigational drugs, biological products, and devices,” ACCESS Act, Sec. 2 (2). Some of the reasoning in support of the purported right of “self-preservation” simply makes no sense: “If there is a protected liberty interest in self-determination that includes a right to refuse life-sustaining treatment, even though this will hasten death, then the same liberty interest must include the complementary right of access to potentially life-sustaining medication...” 445 F.3d 470 (2006), pp., 484-85. Why a negative right to decline and thus be free of presumably invasive life-sustaining interventions entails an entirely distinct, affirmative claim to be given something—i.e., an unapproved investigational drug—is simply not clear.
25. There are other requirements as well. For example, the harm the actor will bring about by violating the law must be less serious than the harm he seeks to avert. See generally Dressler 2009, pp. 289-93.
26. The Model Penal Code, for example, (3.02 (1) (a)), is clear that a sincere belief is insufficient without evidence that violating the law averts a greater harm: “Conduct that the actor believes to be necessary to avoid a harm or evil to himself or to another is justifiable, provided that the harm or evil sought to be avoided by such conduct is greater than that sought to be prevented by the law defining the offense charged.” Kaplan & Weisberg 1991, p. 1182.
29. ACCESS Act, S. 3046, Sec. 3 (d) (7) (emphasis added). The Act would also remove the sponsor’s liability for harm caused
by drugs directly accessed and permit profits from the sale of off-trial INDs. See S. 3046 110th Cong. (2008).

30. Ibid., p. 8.


33. See Fojo and Grady 2009.

34. I want to thank Heidi Malm, Ana Ilitis, Inna De Melo-Martin, Mary Rorty, and the audience at Philosophy and Medicine session of the APA Pacific Division meeting in 2012 for helpful comments.

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What Did “Octomom” Do Wrong?: Exploring the Ethics of Fertility Treatments

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Introduction

For people who suffer from infertility, the joys of having children can be painfully elusive. The development of fertility treatments has made parenthood concrete for those who cannot achieve it by traditional modes of conception. Yet, like many scientific advances, fertility treatments have been misused. Although still rare compared to the birth of singletons, the number of triplets, quadruplets, and other higher-order multiple births (HOMBs) have quadrupled in the past thirty years, mostly due to the increasing use of fertility treatments. In this paper, I will morally assess what I consider to be reckless uses of fertility treatments, using them in a manner that increases the possibility of a HOMB (e.g., implanting a high number of embryos in a womb or engaging in sexual intercourse or artificial insemination when a woman’s ovaries are hyperstimulated) in exchange for expediency when it
comes to getting pregnant, and argue that some restrictions need to be placed upon their usage.

Media attention usually focuses on the successful aspects of HOMBs while ignoring their often negative consequences. The McCaughey septuplets (1997) were born after their mother was treated with the fertility drug Metrodin. Two of the seven children suffer from cerebral palsy, and one has undergone spinal surgery in order to overcome his difficulties walking. Due to her use of Pergonal, Patti and Sam Frustaci (1985) conceived and birthed septuplets; one baby was stillborn and three died shortly thereafter due to respiratory distress syndrome. The remaining three children have cerebral palsy and are mentally disabled.\(^7\) The Morrison sextuplets (2007), also products of fertility drugs, were born prematurely at twenty-three weeks gestational age; five of the six children died within two months of their birth. Most recently (2009), the Stansel sextuplets were born as a result of ovulation induction and IUI. Only two of the six survived, and they face a host of problems even after their five-month stay in the NICU. Because of their prematurity, HOMB infants can suffer from severe physical impairments, such as cerebral palsy, chronic lung disease, strokes, blindness, mental retardation, respiratory distress syndrome, bowel obstructions, and intracranial hemorrhage.\(^4\)

In 2009, Nadya Suleman, derogatorily known as “Octomom,” gave birth to eight babies, all of whom appear, for now, to be in good health. Suleman already had six children under the age of eight, three of whom suffer from disabilities of varying severity, and was not financially independent before the birth of the octuplets. All fourteen children were conceived through the use of IVF.\(^3\) The birth of the octuplets resulted when Suleman asked that the last six embryos from her previous fertility treatment be implanted, and two of the embryos twinned. One of the most concerning aspects of this case is that in each of her six fertility treatments, Suleman was implanted with six embryos.\(^5\)

**Fertility treatments and the nonidentity problem**

Suppose I desire to conceive but am currently suffering from a physical ailment that would result in having an infant with severe impairments. If I were to wait two months, my ailment would pass and I would conceive a perfectly healthy baby. Most people would agree that I should wait those two months; if I do not wait, many people would say that I acted wrongly. Moreover, the resulting child would most likely be identified as the person I have wronged.

This intuitive response, however, is surprisingly tricky to defend. If harm is defined as making someone worse off than they otherwise would have been, it is difficult to maintain that I harmed the resulting child by my actions, even if she were impaired. For the child that would have been born two months later would not have been the same child that is born if I do not wait. Unless the child’s life is so bad that her nonexistence would be preferable, I did not make the child worse off by conceiving her and giving birth to her with those impairments, since she otherwise would not have been born, and thus I did not harm her.\(^7\) This is commonly known as the nonidentity problem, and we must deal with it when clarifying the exact nature of the moral infraction committed by the reckless use of fertility treatments that lead to a HOMB. What, if anything, did Suleman do wrong when she requested that six embryos be implanted at once?\(^20\) If a woman engages in unprotected sexual intercourse, or asks to be artificially inseminated, even though her ovaries are hyperstimulated,\(^9\) is she engaging in any morally objectionable behavior? If one answers in the affirmative, then it seems as if one would have to identify the victim.\(^10\) If the subsequent children would not have been born otherwise, in what sense, then, are they wronged, even if it turns out that they are subjected to a life of impairments as a result of being a higher-order multiple?\(^21\)

Several solutions have been proposed to the nonidentity problem; adhering to any given solution may disparately influence whether or how one morally condemns the use of fertility treatments that may lead to a HOMB. I will focus on two possible responses in this context: a rights-based and a deontological approach.

**The duty of parental responsibility and the correlativity thesis: a rights-based approach**

The rights-based approach eschews the consequentialist definition of “harm” and maintains that an individual can be harmed even if she is not made worse off. Take a musician whose abusive past at the hands of his father allows him to write music that leads him to a life of fame and fortune. Suppose, further, the musician himself agrees that he was better off being abused as a child because he prefers his life of fame and fortune to an ordinary life. Nevertheless, many would hold child abuse is morally wrong, and this does not change simply because a net value of good consequences resulted from the abuse. This is because the nature of such an action, unwarranted violence against an innocent child, suffices to make the action intrinsically morally wrong.

In this case, perhaps, we could point to some aspect of the child’s rights that were violated when he was abused. If someone violates our rights, this is one way that we can be harmed even if we are not made worse off because of the violation. Yet, it is admittedly difficult to take a rights-based approach when discussing children who have yet to be born; for if they do not yet exist, it is tricky to determine whether they currently have rights. I do believe, however, that some right is being violated against a future child in cases such as the ones we are discussing, and we can so argue this by first identifying if there are any preconception duties that parents have towards whatever children they happen to conceive. If it is possible to identify a preconception duty that applies to these cases, then the correlativity thesis between rights and duties can be applied, and we can then identify a correlative preconception right that comes with the preconception duty.\(^12\)

The preconception duty I have in mind is developed by Bonnie Steinbock and Ron McClamrock, which they call the “principle of parental responsibility.”

This principle maintains that in deciding whether to have children, people should not be concerned only with their own interests in reproducing. They must think also, and perhaps primarily, of the welfare of the children they will bear. . . . But where there is no child at all, the question facing the prospective parent is . . . whether to create a child who is likely to have a life marked by pain and severe limitations. It seems to us that the answer to this question must be no. What reason could be offered in justification of an affirmative answer? That the child’s life, while miserable, is not too awful that he or she will long for death? That is not the kind of answer a loving parent could give.\(^13\)

If one agrees with Steinbock and McClamrock that parents have this duty towards any children that result from their preconception activities, then those children have, given the correlativity thesis, a presumptive right to be treated by their parents in a way that fulfills the principle of parental responsibility. And, given that this principle concerns preconception choices, it is a right that exists for any child that comes into existence as a result from those choices. Therefore, if one agrees with the principle of parental responsibility and the correlativity thesis,
it is possible to identify which right is being violated against children that are born impaired as a result of the reckless use of fertility treatments. In such cases, the prospective parents are willing to take a chance of having children whose lives may be marked by pain and severe limitations in order to expediently fulfill their own interests in reproducing.

For those who reject this line of reasoning, we can employ a deontological approach instead. If we still accept Steinbock's and McClamrock's argument that there is a preconception duty of parental responsibility, then adhering to this duty entails a prima facie prohibition against deliberately engaging in actions that knowingly may result in giving birth to children with severe disabilities. 14

What would Ross and Kant say?: a deontological response

According to two branches of deontological thought, Kantian and Rossian, violating the duty of parental responsibility in order to fulfill one's reproductive goals would be morally wrong. According to Russian deontology, duties are prima facie, or conditional, rather than absolute. In situations where prima facie duties conflict, it is permissible to not perform a prima facie duty only if the situation renders another prima facie duty more stringent, and, therefore, my duty proper. If there is a prima facie duty of parental responsibility as defined by Steinbock and McClamrock, violating that duty in order to meet one's reproductive goals is not sufficient to render the violation permissible. In this case, there is no alternative prima facie duty one is opting for; rather, one's own self-interest in reproducing takes precedence. Ross does argue that there are duties to the self, for example, a duty of self-improvement. Perhaps, given one's conception of what it means to have a flourishing life, being a parent is an integral aspect of that conception, and therefore the duty of self-improvement may entail (for some) procreating. For someone who experiences infertility, fulfilling this duty would necessitate some assisted reproductive technology. Yet, there are methods of utilizing this technology in more responsible ways. There is no pressing counter prima facie duty that would justify the reckless use of fertility treatment a la Nadya Suleman. Therefore, according to Rossian deontology, it is not possible to justify violating the duty of parental responsibility in relevantly similar cases.

Moreover, one can argue that Immanuel Kant's second principle formulation of the Categorical Imperative is being violated in such cases. Kant's formula of humanity maintains that persons ought to be treated as ends in themselves, rather than solely as a means. At the time one is making preconception decisions, it is difficult to argue that Kant's imperative is being violated against a child, since no child yet exists. Yet, in some sense, the spirit of the imperative is being violated. Understanding how this is the case necessitates that we see the world from the point of view of the non-philosopher. Most non-philosophers have never encountered the nonidentity problem, and, quite the contrary, they would have little to no hesitancy in maintaining that the interests of future children should be taken into account by parents even before the conception and birth of these children, and even if it entails that no child is conceived or born as a result. 15

On the Stansels' website, there exists a blog that allows for user comments. Quite often, there are comments left that admonish them for not taking “the pain and suffering of extremely preterm babies” into account before they engaged in IUI and while they were deciding whether they should selectively reduce. 16 It is doubtful that these individuals would abate their criticism if they learned about the nonidentity problem and its conclusions. For non-philosophers, rightly or wrongfully, future children are often regarded as current moral patients.

A person who uses fertility treatments recklessly deliberately engages in an action that can lead to a permanently compromised state of health for future children who she most likely already regards as moral patients. She states that the children have in being born as healthy as possible, and the duty that she, as a prospective parent, has in securing that her children are born in the best possible health conditions, is secondary to her procreative interests and desires. She intends, therefore, to treat beings she most likely already regards as moral patients as mere means to her procreative ends. That is not to say that she will not want or love the children once they are born. But it is the willingness to deliberately bring children into the world by any means necessary, even one that may result in them being born in a compromised physical or mental state, which illustrates that the reproductive interests and goals of the parent(s) take primacy. Perhaps it is the case that the child would, in some sense, be “better off” by being born impaired than by not being born at all. But from the deontological standpoint, just because an action may result in a net value of positive consequences does not mean that the action is itself morally correct. It is the nature of an action, not its consequences, that affects its morality. The nature of this action illustrates, at the very least, a violation of the spirit of Kant’s formula of humanity.

On February 10, 2009, NBC aired a Dateline interview with Nadya Suleman. 17 The piece begins by showing her caressing each of her eight extremely premature and sickly looking infants. The voiceover informs us that “Nadya was unmarried, unemployed, and already had six children” at the time she decided to have six embryos implanted in her womb. Her first three children were all singleton births, and she persisted in her desire to have more. When asked why she chose to have so many children, she says: “It was always a dream of mine to have a large family, a huge family. I just longed for certain connections and attachments with another person that I really lacked growing up.” She also admitted that she had full knowledge of the medical consequences that could come with a HOMB. When pressed to answer whether her decision to implant six embryos was fair to her six currently existing children, she answered: “I think there are a lot of things in life that are not fair. It is going to be hard for them. But life, I believe, isn’t always perfect and idealistic.”

From this interview alone, we can deduce at least two ways in which Suleman acted immorally in her procreative decisions. From a Kantian standpoint, the formula of humanity seems to have been violated, for a case can be made that she treated the resulting octuplets as a mere means to her procreative ends. Moreover, she was willing to overlook the welfare of her existing children, essentially asserting that they should just “deal with it,” in order to realize her goals of having a large family and obtaining the emotional connections she felt she lacked as a child, thus treating them as a mere means as well. From a Rossian standpoint, it can be argued that she violated the prima facie duty of parental responsibility; she seemed overly concerned with her own interests in reproducing and she did not seem to think very much about “the welfare of the children [that she] bear[ed].” 18 However, Suleman is, unfairly, being uniquely chastised for a similar procreative decision that has been made by other parents who are usually celebrated. The fact that Suleman already had six children adds an additional dimension of moral dubiousness to her decision, but even without already existing children, the reckless use of fertility drugs in full knowledge of the physical effects it can have on the resulting children is itself morally dubious. 19 Even if it turns out that the children who result from a HOMB are free from any impairments, parents who act in a similar manner in their use of fertility treatments, knowingly increasing the possibility of having a HOMB and the medical, physical, and social complications the resulting children may experience, are equally worthy of admonishment.
How to use fertility treatments in a morally responsible manner

Nothing in this paper implies that the use of fertility treatments simpliciter is morally wrong; there are responsible ways of meeting the needs of the infertile. Some countries, such as the U.K., Germany, Australia, and France, have legally enforceable limits concerning how many IVF embryos can be transferred into a uterus at one time. In 2004, the U.K. passed a law decreeing that only two embryos may be transferred in any given treatment cycle. In Belgium, women under 36 years of age who are in the first cycle of treatment are allowed only a single embryo transfer. In Italy, all embryos that are created via IVF must be transferred into a uterus, but creation is limited to three embryos at a time.21

In the United States, there are no legal guidelines to guide a couple or a physician regarding the use of fertility treatment. In addition to changing the way IVF practices are conducted in the U.S., other types of fertility treatments also need to come under a more watchful eye. IUI in conjunction with ovarian stimulation is the procedure that is most likely to lead to a HOMB.22 Women who take fertility drugs to stimulate ovarian production should be closely monitored, and they should be denied IUI or any type of artificial insemination, and be discouraged from engaging in unprotected sexual intercourse, if there is ovarian hyperstimulation. The latter recommendation, of course, is difficult to enforce. One way to discourage this behavior is to stop the media celebration of HOMBs and, instead, focus on the wreckage left behind in many cases—babies who celebrate multiples “give viewers a misleading picture by failing to ‘view the prospect of triplets or more as a positive outcome to “view the prospect of triplets or more as a positive outcome to [the] chance Suleman had at conceiving.”24

It is time that U.S. policy follows suit with some of its international colleagues in constructing legally enforceable ethical guidelines for the use of fertility treatments. The prevalence of HOMB is not indicative of a massive success in this area, but rather a further example of how humans take advantage of technology without first thinking of the consequences that may result if that technology is abused.

Endnotes

1. For example, in vitro fertilization (IVF), intra-uterine insemination (IUI), gamete intrafallopian transfer (GIFT), oral forms of treatment such as Clomiphene, and injections such as Pergonal.


3. Despite these consequences, the Frustracis were not deterred from using fertility drugs again; in 1990, Patti gave birth to healthy twins after using Pergonal once more.

4. Although this paper primarily focuses on the health of the resulting infants, women who gestate multiple fetuses are more likely to have gestational health problems, often resulting in prolonged periods of bed rest. They are more likely to suffer from high blood pressure during gestation, and they are at higher risk for potentially fatal blood clots during pregnancy and delivery. Additional maternal complications include anemia, preterm labor, hypertension, and postpartum hemorrhage.

5. Because of her scarred fallopian tubes, IVF was the only chance Suleman had at conceiving.


8. And did her doctor, Michael Kamrava, who obliged her, participate in any moral wrongdoing? In this paper, I will mainly deal with how to understand the harm that is being done unto children that result from HOMBs and the subsequent responsibilities the parents of these children have when considering the use of fertility treatments. I will not consider the responsibility of the physicians who administer these treatments, although that topic deserves a paper of its own. The duties that the physicians violate seem different from the duties the parents violate, if only because the nature of parent-child duties differ from the nature of physician-patient duties. There is, of course, also the question of who is the patient in cases of fertility treatments: the parents or the resulting children (or both—but what happens when the requests of the former compromise the health of the latter)? Nevertheless, a case can be made that physicians in these cases seem to be effectuating the desires of the parents rather than following the “first do no harm” principle of medical ethics.

9. This means that she will release multiple eggs during her cycle, rather than the usual single egg. When ovulation is artificially induced, there is no control over how many eggs are released and, if sperm is introduced, there is no way of controlling how many eggs will be fertilized.

10. Of course, it is not only the infants who may be classified as “victims” if they are born impaired as a result of being a higher-order multiple. There is also existing family who will likely suffer (which, as we shall see below, is something Suleman seems to completely ignore), the tax payers who must help pay for the care of these children, health care providers, and even the self-harm that a woman inflicts upon herself by the careless use of fertility treatments. Although this paper only attempts to justify viewing the resulting infants as “victims,” much more can be written about these other groups of possible victims as well.

11. Perhaps the only fertility treatment with the potential to be immune to the nonidentity problem is IVF. Suleman did not have to implant all six embryos at once; she could have implanted only two at a time, for example, and have possibly avoided all the dangers of HOMBs without compromising her children’s identity, since they would all have been born at some point (given, of course, that all would have successfully implanted). Yet for most other instances of fertility treatments, the nonidentity problem is an issue for determining what exactly is the moral wrong done unto these children if they are born with impairments as a result of being a higher-order multiple, given that the alternative is to never have been born at all. If no harm can be identified, then it would seem to follow that fertility treatments should be allowed almost with abandon, despite the possible consequences as described above.

12. Admittedly, the correlativity thesis is a topic of contention; not all philosophers or rights-based theorists agree that there is a corresponding right to every duty or a corresponding duty to every right. However, there are many that do accept the correlativity thesis. For example, in their book Social Principles and the Democratic State, Stanley Benn and R.S. Peters maintain that “[r]ights and duty are different names for the same normative relation, according to the point of view from which it is regarded” (p. 89).


14. What qualifies as a severe enough disability in order to render the decision to conceive a child a dubious one needs to be fleshed out, but it is beyond the scope of my paper to do so. Rather, this is something I would hope we can converse about during the discussion period.

15. This, for example, seems to be the logic employed by the National Research Council when they proposed a ban on human cloning due to concerns that a cloned child, who
Strange Bedfellows: Ludwig Wittgenstein and the National Institutes of Health on the Language of Pain

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Most members of our APA—the American Philosophical Association—will be familiar with Ludwig Wittgenstein’s discussion of pain in his Philosophical Investigations. Most members of another APA—the American Psychological Association—will know about a new approach to the assessment of pain being developed by the National Institutes of Health’s PROMIS initiative. In this paper we will explore the relationship between the two by asking whether the contemporary scientific approach to the assessment of pain is consistent with the remarks Wittgenstein makes about pain in his Philosophical Investigations. Our purpose is not to give anything like a full account of their relationship, but to call the attention of philosophers to this important initiative and suggest some opportunities for dialogue with their colleagues in the social and behavioral sciences.

PROMIS² is an acronym for PatientReported Outcomes Measurement Information System, a multi-year, multi-site, multi-million dollar project sponsored by the National Institutes of Health as part of an initiative “to chart a roadmap for medical research in the 21st century.” Its objective is to develop item banks that measure patient-reported health status in order to standardize clinical research, and ultimately to assist individual practitioners in the clinical assessment of patients.

PROMIS researchers classify patient-reported health status in several domains under the headings of physical, mental, and social health. Pain is included as a symptom of physical health. It is defined as an unpleasant sensory and emotional experience . . . divided conceptually into components of quality (referring to the nature, characteristics, intensity, frequency and duration of pain), interference with activities (impact upon physical, mental and social activities) and avoidance behaviors (behaviors one engages in to avoid, minimize or reduce pain).³

Most of Wittgenstein’s remarks about pain in the Philosophical Investigations are in the sections on private language, which is part of a more extended consideration of how words referring to interior mental acts or experiences are related to their meanings in conventional language. Wittgenstein’s remarks suggest that the traditional view—that the experience of pain is an essentially private experience that only subsequently becomes associated with words to describe it—is based on a misunderstanding of how words acquire meaning.

The procedures used by Wittgenstein and the PROMIS initiative could not be more disparate. Wittgenstein’s research was conducted alone in his chambers at Trinity College or in a desolate village in Galway. The only social aspects to his research involved quizzing a few like-minded friends or engaging close friends in discussion.⁴ His subject is the individual consciousness in dialogue with itself. His intent and methods are often unclear; the structure of his work labyrinthine.⁵ G.E. Moore described his way of thinking in the Philosophical Investigations as “very different from what is required in the sciences.”⁶ However, by all accounts, his work is profound and insightful, though easily subject to misinterpretation.⁷

The PROMIS initiative, by contrast, is big science, involving hundreds of collaborators at dozens of universities. Its purpose, scope, and organization are meticulously laid
The impossibility of creating meaning from purely private sensations is further demonstrated by considering what would happen if each person had a box that no one else can see into.

To demonstrate this, Wittgenstein asks his reader to imagine that someone keeps a diary in which he attempts to record the occurrence of a particular sensation by writing the sign “S” each time he experiences it, trying, as it were, to give himself a private ostensive definition of it. The project, however, is doomed to failure because, as Wittgenstein says, there is “no criterion of correctness”—no way for the person to know whether the sensation he is experiencing is sufficiently similar to prior experiences to warrant the application of “S” to it. There are, after all, certain behavioral criteria for judging that a person knows how to use a word correctly. If a person could show that his writing of the sign “S” has a use—if, for example, he could demonstrate that each time he writes “S” in response to a sensation his blood pressure rises—his sign would have meaning and questions about whether or not he got the connection between the sign and his sensation right would be irrelevant.

With this new theoretical underpinning, psychotherapeutic interventions shift from an event-interpretation model to a narrative construction model. In the event-interpretation model, “therapy is designed to correct distorted interpretations of sensory events.” In the narrative construction model, “the notion that the interpreted event . . . has an independent and fixed reality disappears. Therapy no longer strives to correct distortions, but to construct narratives that promote function.”

Sullivan quotes from a 1985 article by Ronald Melzack, a leading pain researcher. “It is not as if there is one reality and clients distort that reality, thus contributing to their problems; rather, there are multiple realities, and the task for the therapist is to help clients become aware of how they create those realities and the consequences of such constructions.”

What is given, Sullivan concludes, is not the pain event, but a narrative and a form of life within which it occurs. The traditional view that the biological must pass through the psychological to reach the social domain is reversed in that “the social, through language, mediates the relationship between the biological and the psychological.”

With Sullivan’s analysis in mind, we will examine how well the theoretical underpinnings of the PROMIS initiative jibe with the sections on private language in the Philosophical Investigations. It is significant that Wittgenstein’s discussion of private languages follows immediately upon a discussion of measurement. In §242, he says that what we call measurement is partly determined by a certain constancy in its results. This will come to be a crucial element in his critique of private language. If there is no way to know whether a person is using a word consistently to refer to a sensation from one time to the next, Wittgenstein will argue, the word can have no meaning. It will also be seen as a crucial element in the PROMIS initiative’s attempts to validate their item banks. Only when the measurements obtained from them have a “certain constancy” will they be deemed valid measures of pain.

Wittgenstein’s objective in the sections on private language is to dispel the notion that words referring to “inner experiences,” such as pain, derive their meaning simply through association with the experiences they refer to. By “inner experiences” he means those feelings, moods, and the like that “can only be known to the person speaking.” The simplest model for creating an association between a word referring to a pain and the experience of it would be for the individual with pain to “invent a name for the sensation.” While it is obvious that the person in this situation would not be able to make his meaning understood to others, what is not so obvious is that the word would not even have meaning for its inventor.
Suppose the box contains what they call a “beetle.” Since no one can look at anyone else’s beetle, the box might contain anything at all—or nothing for that matter. What is in the box is completely irrelevant. So it would be with pain, if the meaning of the word “pain” were based solely on private sensations.

The meanings of pain words do not derive from associations with pain sensations, but from their uses in language and in “forms of life.” Wittgenstein says that in many cases “the meaning of a word is its use in the language.” He suggests that words expressive of pain acquire meaning through their connections with more primitive natural expressions of pain, such as wincing or crying, and come to be used in their place. “A child has hurt himself, and he cries; and then adults talk to him and teach him exclamations and, later, sentences. They teach him new pain-behavior.” In like fashion, our appreciation of the pain of others is not based on an inference that they experience something analogous to our own sensations, but on our learning to use pain language appropriately in our interactions with them.

The PROMIS researchers’ treatment of pain is generally consistent with the approach implied in Wittgenstein’s remarks although there are some aspects of the relationship between pain and language identified by Wittgenstein, but not mentioned in the PROMIS literature, that suggest lines of inquiry for future research.

Consistent with Wittgenstein’s statement that the meaning of a word is determined by its use in language, the terms used in the PROMIS domain names and item banks were selected primarily for their utility. PROMIS researchers began by developing a “domain map” or conceptual framework for conducting their research in order to identify “the most useful response sets.” Then they built “libraries” for each domain by collecting items from existing questionnaires and classifying them according to their content. Once sets of candidate items were sorted into domains, the researchers eliminated items that were redundant or did not fit in the domain to create smaller sets for field testing. These activities (called binning and winnowing) were carried out through a process of expert consensus.

Although utility was their primary concern, the researchers also considered comprehension and exactness of representation. They aimed to identify “items that cover the range of experience in the domains to be measured and items that can add precision to the final estimate of the latent trait.” The term “latent trait” here refers to what is being measured by the item bank—pain, fatigue, quality of life, etc. Traits are latent in the sense that they are not directly observable.

To validate the relevance of their questions to the experiences of potential respondents, PROMIS researchers used focus groups and cognitive interviews to get feedback regarding the “current conceptualization of each domain.” Their purpose was to “improve the likelihood that our items will be understood and interpreted as intended,” and to “improve the chance that our items reflect important patient experiences.”

The researchers used focus groups comprised of patients of various ages, cultures, conditions, and experiences to discover the vocabulary and thinking patterns of the target group. It was important, the researchers said, “to make sure we were addressing topics that reflect how potential respondents experience the world.”

Cognitive feedback interviews were used to determine what “the specific words and phrases in the question mean to the respondent.” Although the researchers recognized that “many respondent characteristics may be associated with different interpretations of items,” they focused initially on differences according to reading level, educational level, racial group, and diagnosis. PROMIS researchers thus avoid many of the problems identified by Wittgenstein. While acknowledging the “latency” of the traits they intend to study, they explore the link between PROMIS definitions and the interior experience of potential respondents by querying groups of individuals who are highly likely to have experienced the condition they are trying to measure, using words that are common in the language. It makes no difference to their analysis what the private experience of people might be; the only thing that makes a difference is how they describe it.

The development of two item banks related specifically to pain have been described in the PROMIS literature, one related to pain interference and the other related to pain behavior. Both of these item banks were subjected to the qualitative reviews we have just described. In addition, they were evaluated quantitatively in terms of their psychometric properties. The pain interference item bank started as a library of 644 items drawn from existing questionnaires which were eventually winnowed down to 41. As part of their qualitative review, researchers interviewed persons who had experienced pain “to ensure that [items] were meaningful to and easily understood by individuals living with pain.” Persons interviewed were selected from clinical settings and disease registries.

The pain interference item bank was administered to a large sample of 14,848 respondents and a smaller sample of 1,055 individuals who were “likely to experience chronic pain.” These latter were recruited from cancer clinics and the American Chronic Pain Association. In addition to the item bank, respondents were questioned about their general health and the intensity of their pain.

Responses were analyzed using a unidimensional item response theory (IRT) model. According to Wikipedia, IRT models are also referred to as latent trait models. Responses to questionnaire items are “taken to be observable manifestations of hypothesized traits, constructs, or attributes, not directly observed, but which must be inferred from the manifest responses.”

A unidimensional IRT model is based on “the assumption that a single latent construct drives the variance in scores.” In their article on the PROMIS initiative, David Cella and his colleagues explain that there are two fundamental assumptions embedded in unidimensional IRT models: “that a single trait determines how people respond to items and that those items are locally independent, that is, there should be little association between responses to 2 items beyond that accounted for by the underlying trait.” A confirmatory factor analysis was used to verify unidimensionality. The analysis revealed that pain interference accounted for 86 percent of the variance, a strong indicator of unidimensionality.

These psychometric techniques are based on a mathematical model that “allows comparison of the patterns of actual responses to those predicted by the model. How closely the actual data correspond to the predictions of the model can be quantified and summarized by goodness-of-fit statistics. These statistics compare expected and observed frequencies of item category responses for various levels of scores and quantify the differences between [them].”

The construct validity of the item bank was then evaluated by comparing pain interference scores to the scores on surveys of other similar domains and to global health and pain intensity ratings. Construct validity was confirmed by demonstrating that variances in the pain interference scores distinguished among subgroups differentiated by the number of chronic and disabling conditions and ratings of global health and pain intensity. In fact, “the scores increased stepwise with increases in number of chronic conditions, disabling conditions and decreases in reported general health.”
Finally the item bank was evaluated in terms of differential item functioning, which examines differences “based on subgroup membership.” The authors explain that “in the context of pain interference measurement, persons of different ages, education levels, race/ethnicities, and genders who have equal levels of pain interference should be equally likely to endorse a particular category of a specified . . . item. For example, men and women who are equal in their levels of pain interference should be equally likely to respond ‘somewhat’ to the item ‘how much did pain interfere with work around the house?’” Apart from a few items related to gender and age, no significant differential item functioning was detected. The authors acknowledge that “it would be useful to expand the evaluation to additional subgroups” based on specific pain conditions, health conditions, or ethnic/racial identity.

The cumulative result of all this testing was the conclusion that these “items constitute a psychometrically sound item bank for assessing the negative effects of pain on functioning in the range experienced by the vast majority of people who have pain.”

The same techniques were used to validate a pain behavior item bank. Although the most objective approach to the measurement of pain behavior is direct observation, the use of patient reports of pain behavior is easier, faster, and less costly. The qualitative and quantitative reviews were identical to those used for the pain interference item bank and yielded analogous results.

By confining themselves to the publicly observable realm of language use, the PROMIS researchers remain remarkably exempt from Wittgenstein’s critique of the notion that pain words derive their meaning from association with private pain sensations.

Their quantitative methods reveal patterns of relationships among survey results that are reliably indicative of variations in the “latent traits”—such as pain or pain interference—they are attempting to measure. The latent traits appear in their literature, not as sensations, but as “constructions” fashioned out of words in ordinary use. The link between the “pain construct” and the “pain experience” is interpreted not in terms of formal identity or correspondence, but in terms of reference and relevance to the experiences of people in pain.

The fact that the construction of instruments to measure pain depends on validation by people identified as being in pain seems to involve a vicious circle. How can people be known to be in pain unless their pain can somehow be ascertained? The PROMIS researchers skirt this issue by selecting samples from among people who are most likely to be in pain: patients with cancer, members of the Chronic Pain Association, and the like. No doubt there will be variations in the intensity and types of pain they experience, and no doubt some will have hidden motives for exaggerating or minimizing their pain, but taken as a whole, as a representative clinical sample, the variations will fall into place along the predictable curves of statistical models.

However, despite their appreciation of the social aspects of pain language, the PROMIS researchers seem to be somewhat short-sighted about potential differences in the way pain is described or expressed across cultures. They tested for differential item functioning across educational, gender, age, and simplistic racial and ethnic categories, and obtained a few relatively insignificant results. Although they acknowledged that “it would be useful to expand the evaluation to additional subgroups,” the few they mentioned—specific pain conditions, health conditions, or ethnic/racial identity—may not be the most relevant.

A more fruitful line of inquiry might be to test for differences among subgroups who may be culturally conditioned to use pain words differently. For example, there may be systematic differences in the way pain is expressed among military personnel or serious athletes, requiring recalibration of the item banks when they are used in military or sports medicine. For the same reasons, instruments might require independent validation for use in prisons, drug rehabilitation programs, or other communities with unique “pain narratives.”

Another area for future research suggested by Wittgenstein’s investigations is related to the various ways the PROMIS instruments might be used. The researchers are clear that their primary intent is to create instruments for use in clinical research, but one team expressed a hope that they “may also assist individual practitioners in assessing patients’ responses to interventions and modifying treatment plans on the basis of these responses.” Another team expressed a desire to associate changes in scores with actionable events, such as changes in medications or referral to specialists.

Using PROMIS item banks to help guide individual clinical practice represents a significant change in the use of or function of the item banks, which may or may not affect the meaning of the terms involved. At first glance, it seems plausible that the meaning of the items would remain stable whether they are used in a research or clinical setting, but Wittgenstein’s remarks about meaning as use-in-language should alert us to the possibility that a shift in use might result in a shift in meaning. In a research setting it may generally be assumed that respondents’ responses represent authentic attempts to describe or report their pain; but in a clinical setting their responses may be more like expressions of pain than reports of it, more help-seeking than objective, and more prone to manipulation than they might be in a research setting.

Wittgenstein suggests that the meaning of words can shift when they are used in different language games. To use a familiar example from an early section of the Philosophical Investigations, the phrase “five slabs” means one thing when it is used to report the presence of five slabs and another when it is used to order someone to bring five slabs. Similarly, the phrase, “I have so much pain I can’t get out of bed in the morning” may have one meaning as a factual report of pain interference and another as a plea for additional pain medication.

At a practical level, this suggests that the PROMIS item banks—like any other rating scale—should be used in clinical practice only in the context of a more comprehensive assessment of the patient’s pain and health status. Researchers may find it helpful to develop protocols and techniques for detecting dissimulation or manipulation when item banks are used clinically and they may find it useful to retest their tools for validity in clinical settings.

A final comment. In the preceding remarks we have been considering the implications of Wittgenstein’s critique for the PROMIS initiative; but we should note that the approach taken by the contemporary scientific community might help philosophers gauge the meaning and validity of Wittgenstein’s remarks.

The fact that the scientific community has taken an approach to the measurement of pain that is so consistent with Wittgenstein’s remarks suggests that despite their perplexing character, Wittgenstein’s comments may have meaning for a real-world health care initiative. To appreciate the implications of the PROMIS literature for an understanding of Wittgenstein, however, it will be necessary to look more closely at the links between the methods used by the researchers and the grammatical therapies offered by Wittgenstein.

The epistemological problems that inspire many of Wittgenstein’s comments—questions about how individuals conceptualize their own pain or come to know the pain of
others—are addressed, sometimes implicitly, in the methods used by the researchers. The techniques of creating domain maps, collating existing item banks, binning and winnowing, focus groups, cognitive interviews, IRT analyses, construct validation, and the evaluation of differential item functioning, all converge on the questions of how pain is conceptualized and measured in a way that is precise, reliable, and reflective of the other’s experience.

The difficulty for philosophers (or at least for this philosopher) lies with the technical complexities of the psychometric methods used by modern behavioral scientists, which to the naive observer can look like epistemological sleight of hand. The task the behavioral scientists have set for themselves—to demonstrate that their instruments are valid measures of traits which cannot be directly observed—cannot be accomplished using simplistic methods or simplistic notions of validity. It behooves us then to acquaint ourselves with these methods and this literature if we are to explore the meaning of pain and other latent traits without falling into the conceptual traps that Wittgenstein has pointed out to us.

Endnotes

1. This address is in the spirit of Wilfrid Sellars’ comments about “knowing one’s way around” in “Philosophy and the Scientific Image of Man,” in Frontiers of Science and Philosophy, edited by Robert Colodny (University of Pittsburgh Press, 1962).

2. Information about PROMIS is accessible at http://www.nihpromis.org/ (October 14, 2011).


4. An item bank is a set of “carefully calibrated questions that define and quantify a common concept and thus provide an operational definition of a trait.” Ibid.


10. Garth Hallett, A Companion to Wittgenstein’s “Philosophical Investigations” (Cornell University Press, 1977) and P.M.S. Hacker, Wittgenstein: Meaning and Mind, Vol. 3 (Basil Blackwell, 1990), xvi. To avoid these dangers, we will stay on the better travelled roads, avoiding, to the extent possible, the darker, dakerer precincts.

11. The principal Internet address for PROMIS is http://www.nihpromis.org/.


13. Ibid., 3.


15. Ibid., 11.

16. Ibid., 4.

17. Ibid., 3.

18. Ibid., 7.

19. Ibid., 5.

20. Ibid., 8.

21. Ibid., 10.

22. Ibid., 12.


25. We are cognizant of the warning issued by P.M.S. Hacker that “as one plunges into the tropical undergrowth of the great private language arguments, it is all too easy to lose one’s bearings. The path is overgrown with prevalent misinterpretations, and dark distorting shadows are cast across it by our disposition to extract theories from Wittgenstein’s descriptions.” Wittgenstein: Meaning and Mind, Vol. 3 (Basil Blackwell, 1990), xx. To avoid these dangers, we will stay on the better travelled roads, avoiding, to the extent possible, the darker, dakerer precincts.


27. PI, §257.

28. PI, §257.

29. PI, §269.

30. PI, §270. I follow Hacker’s interpretation of this section. Hacker, 133-137.

31. PI, §43.

32. PI, §244. It is interesting to note that Wittgenstein reads the distinction between exclamations and sentences back into the process by which adults teach children to express pain in words. While exclamations may be more spontaneous forms of expression, it is unlikely that adults teach children exclamations first and introduce sentences only later.

33. While we cannot know the object of Wittgenstein’s critique for certain, Marie McGinn’s suggestion that it is the introspective approach advocated by William James is plausible, although she may have overstated James’s trust in introspection. While he says that “Introspective Observation is what we have to rely on first and foremost and always” (The Principles of Psychology [Dover, 1950], 185) he also concluded that “introspection is no sure guide to truths about our mental states” (p. 157). James was well aware of the “Misleading Influence of Speech” and the grammatical confusions it may cause.

34. Cella 2007, 5.

35. Ibid., 6.


37. Ibid., 9.

38. Ibid., 7.

39. Ibid.

40. Ibid., 8.


42. Ibid., 174.

43. Dewalt, 8.


45. Amtmann, 176.

46. Cella et al., 7.

47. The authors note (p. 179.) that “Responses to self-reported items measuring complex constructs are never strictly unidimensional,” although analyses support the conclusion that it is a homogeneous construct.

48. Ibid., 176.

49. Ibid., 178.

50. Ibid.

51. Ibid., 178.

Perceiving Sympathetically: Moral Perception, Embodiment, and Medical Ethics

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1
Several months ago, I began having severe chest pains. The pain was entirely on the right side of my chest, and felt “deep”—that is, it felt unlike a muscular issue, and equally unlike the pain typical of a broken (or bruised) rib. There were, however, some similarities: pain increased as I raised my arms, as I took deep breathes, and as I moved my torso in otherwise regular ways.

In the course of a week, I twice went to the emergency room. Oddly, I was already deeply involved in the issues that this paper will take up—particularly in issues involving the connection between our bodily existence and our perceptual reality. On each visit, I was subjected to a battery of tests. Electrodes were connected to several points on my body to take a “picture” of the activity of my heart; I was injected with a dye and then scanned by an fMRI; I received more run-of-the-mill chest x-rays. As I waited for each new test, I was hooked up to a small device, worn on my finger, to monitor my pulse. I was likewise given an IV, fitted with a standard device for measuring blood pressure, and given a supply of oxygen (through tubes behind my ears).

In clinical contexts, one’s body stands out in a decidedly different fashion: it comes to the forefront of our awareness in a way that, under normal circumstances, would impede action. The body is, in our daily actions, what has been called “the absent present”: it is the unthought presupposition of all action and cognition. The decision to open a window, for example, can be said to come to the forefront of our awareness in a way that no other activity of the mind can be. This decision can be made for the view that this is a kind of bodily training).

2
It is a truism that the body is important to ethics—and even more so to say that it is important in medical ethics. Medicine deals fundamentally with the body, albeit sometimes indirectly, and marks one of the more obvious contexts in which the way one experiences one’s body is itself of concern. As David Schenck has argued, the intimacy of one’s body to oneself is so deep that there is indeed seldom any distinction to be made between myself and my body—this intimacy means that all invasions of the body are extraordinarily serious matters . . . . [This] is strikingly apparent in the elaborate rituals, conventions and safeguards found throughout medical practice. For medicine is pre-eminently the practice of invading that most fundamental dimension of our lives—our bodies. (45)

In instances of illness, disability, and disorders, the body is the very focus of the attentive gaze: it is both one’s very being-in-the-world—something that cannot be a mere object, as well as the object that must be depersonalized to be diagnosed—even if only momentarily. What is at stake in health care—whether a planned surgery, an emergency room visit, or even a routine check-up—is immense. We are acknowledging our own bodily nature, and thus exposing ourselves to an embodied reality we so routinely, and thankfully, forget. Schenck makes the point as follows:

For it is only through the body that we are present in the world, only through the body that we carry out projects in the social and physical worlds, only through the body that we have a self. Medical personnel are
responsible for all of this in the life of every patient who passes under their hands. Every patient risks all of this every time he or she goes under the hands of a doctor or a nurse or an orderly. (Schenk, 49-50)

In this intimate encounter—where I am exposed in my embodiment to the clinical gaze—we find the heart of a medical ethics that cannot be reduced to rules and regulations, even if such rules and regulations must be accorded their proper place. Schenk once more:

> It is the texture of bodily being that gives to medicine as social practice and to medical ethics as social discourse their particular and distinctive features. Going into discussions of medical ethics attending only to ethical theories, without attention to the phenomenon of embodiment, would be like going into a discussion of the rules governing football games without paying attention to the differences between football, basketball and baseball, focusing only on abstract discussions of the nature of “rules” and “games” as such. Too often ethicists of medicine seem lost in just this way, and that is because they tend to ignore that which distinguishes medical ethics from business ethics or legal ethics—which is, of course, the centrality of the body for the practice of medicine and the texture of embodiment of human life itself. . . . It is this centrality of the body that demands the special obligations of health-care professionals and that calls forth the special anxieties and, occasionally, the deep gratitude of patients. (50-51)

A focus on our embodiment generates a host of moral issues that are not easily subsumed in ethical guidelines. It is difficult, to put it mildly, to interpret, to implement, and to assess moral guidelines of the form “Recognize the fundamental embodiment of the patient, and the centrality of this embodiment to the patient’s agency” or even “Treat patients with sympathy.”

This does not, however, mean that the reality of embodiment, or the moral issues it occasions, are somehow avoidable. In an appropriately Aristotelian mood, we all recognize that rules cannot replace understanding, and that what can be assessed isn’t the same as what matters.

3

The predicament of the patient is at the core of the medical situation. As I lay in the emergency room (twice) most recently, I was of course concerned that my body was not functioning as it should. But this claim under-describes my anxiety. My being-in-the-world itself was threatened—not just who I am—not even the precise manner of my embodiment—but the entire network of relations and values that constitutes my life—that gives significance to all my thoughts and endeavors. “What will my children do if my condition is terminal?” I repeatedly thought, “How will they cope with my demise?” These are questions that mere diagnosis—cold, clinical, mercilessly practical—cannot answer. And it is this threatened being-in-the-world, I am suggesting, which makes the clinical encounter fundamentally an ethical one. Seeing the symptoms of the patient as discrete bits of data to be assessed—to see a condition in front of one—is thus to pay too minimal attention to the endangered agency of the patient.

Consider the following (actual) case: a woman brings her husband into the emergency room. The night before, her husband was having some knee pain. By the following afternoon, he was unable to walk without assistance. A trip to the family doctor ended with the advice “wait it out.” By that evening, the husband had to be carried into the emergency room. A battery of tests soon revealed that he had been infected with a flesh-eating bacteria. His left leg and hip were removed. When the surgeons met with his wife (and adolescent children) following the emergency procedure, they offered only that the husband would almost certainly die—that the surgery had not happened soon enough. The “consultation” after the surgery lasted no more than two or three minutes. The doctors recited the facts, as if naming the items on a grocery list, and then quickly left the waiting area.

To my mind, this constitutes an ethical breach. The failure here is not one of rule-violation. The doctors were honest to a fault; they were not intentionally cruel or misleading. What was lacking in this clinical encounter, it seems, was more the appropriate manner of approaching the patient’s loved ones. What was needed was not even to say something other than what was said. Rather, the failure here was one of phenomenology—the doctors failed to convey any kind of sympathy to the family of the man they had just amputated, and who they thought would soon die.

Sympathy can be conveyed in language, it is true, but it is more often conveyed in non-verbal ways. To be sympathetic just is to perceive sympathetically—to see the distress and anxiety in those one encounters, and to respond appropriately. To reiterate: responding appropriately need not involve offering verbal condolence. Most frequently, our emotional attitudes toward others are conveyed beneath the level of reflective self-consciousness. We display our sympathy rather than state it. Indeed, to state that we are sympathetic sometimes has a hollow ring to it—as though one must say it because it isn’t already obvious. And for all the pressures already on health care professionals, I want to add this one as well: those in the healing professions have a duty to cultivate their ability to perceive their patients sympathetically.

Sympathy is one of the moral emotions. On one view—and one I endorse—emotions themselves are forms of perception. It follows, given this and the considerations offered above, that health care professionals have an obligation to perceive their patients in a certain way. Of course, making claims such as this often incites philosophical indignation, and this on two fronts: first, it is claimed that one is only morally obligated to act in a particular way—that the domain of ethics does not extend to attitudes until these attitudes produce concrete actions. Only then can we criticize an agent. Second, to claim that sympathy is a kind of moral perception seems to involve abusing a metaphor: sympathy involves judgment, not perception. It will prove useful to meet both of these challenges head-on.

4

Do attitudes matter if they do not result in actions? Much literature on moral perception, as well as every standard virtue ethics, suggests that they do. Iris Murdoch insists on the point throughout The Sovereignty of the Good, much of which is guided by the following example.

A mother, whom I shall call M, feels hostility to her daughter-in-law, whom I shall call D. M finds D quite a good-hearted girl, but while not exactly common yet certainly unpolished and lacking in dignity and refinement. D is inclined to be pert and familiar, insufficiently ceremonious, brusque, sometimes positively rude, always tiresomely juvenile. M does not like D’s accent or the way D dresses. M feels that her son has married beneath him. Let us assume for purposes of the example that the mother, who is a very “correct” person, behaves beautifully to the girl throughout, not allowing her real opinion to appear in any way. . . . M observes D or at least reflects deliberately

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about D, until gradually her vision of D alters. . . . D is
discovered to be not vulgar but refreshingly simple,
not undignified but spontaneous, not noisy but gay,
ot tiresomely juvenile but delightfully youthful, and
so on. . . . M’s outward behavior, beautiful from the
start, in no way alters. (16-17)¹

Murdoch aims to show us that “outward appearance” doesn’t
capture everything that matters to moral assessment. Similar
conclusions can be drawn in considering attitudes like misogyny
and racism, as Lawrence Blum has argued. For reasons that
will become clear, I am inclined to think that the emotional
elements of attitudes are never completely separable from
actions, not because we always decide to act on some attitude,
but because our emotions are perceptually available. Our
emotions are not hidden beneath the skull, but present in
the timbre of our actions, even when we make an effort to
conceal them. Given that attitudes are not simply emotional,
however, they must still be assessed apart from their “outward
appearance,” as Murdoch suggests—even after we’ve extended
“outward appearance” to include the way that emotions display
themselves in our inflection, our body language, and in the
countless ways in which animals communicate with their bodies,
unbeknownst to any reflective consciousness.

Rather than pursue this point (I have argued for it
elsewhere), I want to turn to what I regard as the more stubborn
philosophical prejudices surrounding the notion of perception.
In providing a richer account of perception, I think, we will
be able to set aside many of the objections to the idea that
there can be an obligation to develop the ability to perceive
sympathetically.

Inevitably, when the phrase “moral perception” is
employed, one must face the standard battery of objections:
perceptions require a dedicated sensory input and modality—
eyes see, ears hear, but there’s nothing that “perceives” the
moral; perceptions must attach to things in the world—we
see color, hear sounds, and so on—but there are no “moral
properties” in situations, there thus cannot be moral perception;
relatedly, perceptions are non-inferential, and moral perception
seems to require inference.

Most of the objections raised against moral perception
relate to the use of the word “perceive.” These objections
depend on a fairly standard (and faulty) conception of the nature
of perception. The first common prejudice is a commitment to
the standard set of five senses, each of which operates in relative
isolation from the others. Synaesthesia is thus exceptional (I
see distance, hear sound, and taste flavor—one cannot hear
distance or see with one’s tongue on the standard view). Each
sensory modality picks out its unique property. This basic
picture is (seemingly) captured by Aristotle, who posits a
“special-object” for each sense—an object about which that
sense could not be wrong.

I call “special object” whatever cannot be perceived
by another sense, and about which it is impossible
to be deceived; e.g., sight has color, hearing sound,
and taste flavor, while touch has many varieties of
object . . . it is the special objects which are objects of
perception properly, and it is to these that the essence
of each sense is naturally relative. (On the Soul, 176-
177; 418a11-26)

But, as is often the case in our common sense notions, the
insularity of the senses turns out to be grossly exaggerated.¹
Two examples suggest that synaesthesia is the rule, and isolated
sensory functioning is the exception. One can hear distances,
it turns out—and one can see with one’s tongue. Research on
human echolocation shows that we do in fact echo-locate,
though we ignore this ability due to what Aristotle called our
love of sight—the feast of the eyes, we might say (employing a
synaesthetic metaphor), starves the other senses. Nevertheless,
our capacity to echolocate can be developed, and it can be
developed to such an extent that we can utilize it to navigate
space, to detect objects, and to distinguish those objects. In
this respect, we can hear distances, hear objects, and hear
landscapes. In such cases, the “special object” of sound seems
best described as capable of picking out what would otherwise
be visual properties.

The explanation of such phenomena involves a recognition
of deep neural plasticity—the ability to “re-wire” the pathways
of the brain to accommodate and negotiate sensory stimuli
of all varieties. This ability is not in fact limited even to what
we are already naturally doing—we all echolocate naturally,
though we have not developed our abilities in this regard simply
because we do not need to. We do not, however, all already
see with our tongues—or with our backs—but it turns out that
this, too, is possible.

In 1972 Paul Bach-y-Rita pioneered the use of TVSS
(Tactile Visual Sensory Substitution). This was a device
worn on the back but connected to a camera worn on
the head. The back pack consisted of an array of blunt-
ended ‘nails,’ each nail activated by a region of pixels in
the course visual grid generated by [a] camera. A more
recent descendent of this device uses a much smaller,
electrical stimulatory grid, worn on the person’s
tongue. Fitted with such devices, subjects report that
at first they simply feel the stimulation of the bodily
site (the back or the tongue). After extensive practice,
in which they actively manipulate the camera while
interacting with the world, they begin to experience
coarse quasi-visual sensations. After a time, they cease
to notice the bodily stimulations and instead directly
experience objects arrayed in space in front of the
camera. If the camera input, for example, presents
a rapidly approaching object [by presenting a rapidly
expanding tactile grid] . . . the subject will instinctively
duck, and in a way appropriate to the perceived threat.
(Clark, 125-126)

The tongue, it turns out, can do much more than talk and taste.
The idea that the tongue can have only one kind of sensory
object, then, is false. This, in turn, dismantles the idea that
there can be no moral perception because there is no unique
sense-organ to accomplish the perception.

A second common prejudice is more philosophical in
nature. It is the view that what we properly perceive is “sense-
data,” in the sense of that term made famous by Bertrand
Russell. On this view, we only actually perceive small bits
of sensory information. We then have to piece together this
sensory information through judgments about what the sensory
information represents.

No one—not even Bertrand Russell—would deny that
this view gets the phenomenology all wrong. We very rarely
experience sense-data consciously, and it is equally rare for
us to experience making a judgment about what the sensory
data represents. I experience tables, people, roads, etc.—this
is the character of my experience. I do not experience “splotches
of color.” But to this phenomenological reply, we are always
met with the reassurance that the process (seeing sense-data
and then judging it to be some particular thing) is entirely
unconscious. We “infer” and “judge” things quite apart from
ever knowing we’re doing it, or so the story goes.

But let us leave aside this bizarre reply momentarily. There
are more pressing problems with the standard sense-data
theory—problems well-known for at least a century. It turns out that sensory input is structured by our expectations, by our current tasks, and by context. The Phi Phenomenon, change blindness, and the tendency of the brain to "fill-in" perceptual information based on what one is currently doing—these are common enough reasons to reject a theory that posits sense-data as the ultimate perceptual unit. If we simply perceived sense-data, it would be very difficult to explain why we are so bad at noticing slow changes in the situation around us. If we simply perceive sense-data, it becomes even more difficult to explain the task-oriented nature of perception—to explain why so many don’t see the man in the gorilla suit as they count the number of times a basketball is passed between players (in the "invisible gorilla" experiment).

The lesson to be drawn from this is that perception is much more holistic than we often think—both in terms of how we perceive (synaesthetically) and what we perceive (gestalts, contexts, situations). Once we acknowledge that perception is context-specific, and that we need not have particular senses tracking particular properties uniquely, it becomes much more natural to think of sympathy as a kind of perception.

To see just how limited the sense-data theory is—even when it’s stuck in the back door—consider some research on neo-natal imitation. According to several studies, neo-nates can imitate other human beings in simple ways as early as forty-two minutes old—and perhaps from moments after birth. As Gallagher notes, “in complete contrast to [the] traditional view, studies on imitation in infants conducted by Letzoff and Moore (1977, 1983) show that invisible imitation does occur” (69), where “invisible imitation” is defined as “the child’s imitation of another person’s movements using parts of the child’s body that are invisible to the child [primarily, the face]” (68). “Their experiments, and others that replicate and extend their results . . . show that newborn infants less than an hour old can indeed imitate facial gestures” (69).

Gallagher’s aim in considering these experiments is to argue that the body schema is innate—that we are aware of how to move our bodies prior to an out-of-the-womb experience, and hence that a pre-reflective understanding of ourselves as embodied exists even prior to birth. But there is another, broader lesson to be drawn here about the nature of perception in its infancy. Even at birth, we do not experience sensory data and then make inferences about that data to judge what we are experiencing. From just minutes out of the womb, the human infant perceives bodily possibilities. In seeing other human beings, we perceive their purposive behavior, and we see it as though looking in a mirror. When we see the other act, we see possibilities for ourselves, and we see them directly and immediately.

Or do we? The standard reply surfaces here as well: the infant is engaging in pre-reflective inference. Properly speaking, without sensory input, such imitation would not occur (by definition, as we’d perceive no one to imitate). The same sensory input should produce the same effects. To explain why infants imitate some gestures and not others, we require some internal mechanism (we’ll call it inference) by which some set of sensory information translates into a judgment of the purposiveness of what one sees—and all of this, we are told, happens at the level of the adaptive unconscious.

As is probably obvious, I have little sympathy for this view. An inference has a phenomenological signature, and once we’ve jettisoned these alleged inferences to a realm where the phenomenologist finds no data (the unconscious), it’s hard to know what exactly is being said when one appeals to unknown inferences being made mechanistically.

But it is as you like it. What matters here, in my view, is not whether or not there exists something properly called “unconscious inferences.” We can say what we choose. What matters, rather, is that the perception of purposiveness is phenomenologically immediate at this early age. What will not do is to claim that the one-hour old infant is making reflective judgments about how the world is—the newborn infant hasn’t even yet got a notion of permanent objects, or a language within which to reason, or the synaptic wherewithal to process premises and conclusions. This means that, whatever else is going on in the autonomic brain, the infant is perceiving purposes and bodily possibilities. And this means that our perception of others, at the earliest stages of life and onward, involves a perception of contextual richness that cannot be accounted for by a sense-data theory.

We are even beginning to know something about how this kind of perception functions in the brain. As Gallagher notes, “mirror neurons link up motor processes with visual ones in ways that are directly relevant to the possibility of imitation” (77), strongly suggesting that perception is “intermodal,” or “synaesthetic.” When we watch other agents act, it turns out, we activate the very parts of our brain responsible for carrying that act out ourselves. It is as though, when we perceive someone carrying out basic motor functions, we also immediately understand those actions as among our own possibilities.

Mirror neurons respond both when a subject performs a particular (goal-oriented) action involving arm, hand, or mouth and when the subject observes such actions being done by another subject. This class of neurons thus constitutes an intermodal link between the visual perception of action and dynamic expression, and the intrasubjective, proprioceptive sense of one’s own capabilities. (Gallagher, 77)

What much of this kind of research suggests is that we can literally perceive the emotional states of others. This, I have already suggested, is the very heart of sympathy—of the primordial connection between agents that Max Scheler spent so much time fruitfully excavating. As happens with surprising frequency, the phenomenologist anticipates the neuroscientist. Commenting on findings in the neuroscience literature, Michael Gazzaniga has remarked that research has demonstrated repeatedly that people tend to respond to the sense of taste, touch, pain, fear, joy, and excitement of others with analogous physiological activation patterns of their own. They literally feel the emotional states of others as their own. (175)6

Perhaps ironically, given my earlier criticism of Aristotle on perception, Aristotle himself recognizes that the kinds of perception available to us are not exhausted by sensory perception. Practical wisdom, Aristotel contends, involves a particular way of seeing the world:

[Phronesis] is of the ultimate particular, of which there is not scientific knowledge but perception—not sensory perception, but like the perception whereby we perceive that the triangle is the ultimate particular in geometry (Nicomachean Ethics, 1142a27-29).

It is precisely this notion of perception, I think, that makes sense of a much-loved phenomenological insight: sympathy itself is a kind of perception, and it is basic to human experience. Sympathy is “basic” in the sense that it cannot be explained simply in terms of the single modalities of other senses, and it involves processes the beginnings of which are present at birth. Once we’ve abandoned Mackie’s queer idea that there must be “moral properties” picked out by a unique “moral faculty,”
we can begin to see with some ease how perception involves things like context, situation, possibility, and value. We can further see how perception can be developed through training. We can learn to taste the characteristics of wine, to improve our echolocation, to see the sex of newborn chicks at a glance, to hear a minor scale, and much more besides. We can also learn to develop our ability to perceive sympathetically. We can harness and develop our immediate responsiveness to the needs of others—we can learn to see suffering and the need to respond to it rather than simply hoping we have the time to make the inference that it’s there.

On this view of perception, then, perception is always the perception of contexts (not discrete bits of sensory information). We perceive contexts, and we perceive them in light of the salient features of those contexts—features which stand out (or fail to stand out) based on the purposive possibilities embedded in the situation itself, along with our preparation to notice those embedded possibilities. To cultivate sympathetic perception, then, is to cultivate an appropriate responsiveness to those situations of need we encounter. As we have seen, one such situation of dire need is the medical one.

Given the predicament of the patient, I have suggested, part of the moral responsibility of the physician, the nurse, the orderly, and even the volunteer, is to cultivate what I have called “sympathetic perception.” I have also suggested that this won’t be accomplished by including rules that demand sympathetic perception. Much medical ethics has placed an emphasis on rules and principles, the adherence to which marks the moral. Medical ethics boards are often asked to “clarify” moral principles and rules when they are in tension, after which doctors (and other practitioners) simply choose the principle they find most appealing—a process that may well reflect theories being chosen because of how they resolve a case rather than for any kind of intrinsic merit.

There is a certain utility to teaching rules to emerging medical health professionals. The value in doing this, it seems to me, is one that Aristotle saw most clearly: learning standard rules habituates one into thinking in terms of particular values, and such habituation thereby increases our ability to detect situations where those very values are at issue. Moreover, rules are eventually internalized, and moral judgment can become moral perception.

But this emphasis comes at a cost: as we all know, rules can become fetishized. Substantive conversations aimed at solving multi-valenced and complex problems give way to obstinate grandstanding and an inattentiveness to particularity. For as much as rules can help us to navigate new waters, they can also lead us to become more obsessed with the equipment of navigation than with the waters themselves. Complex issues are not seen for what they are, but are rather regarded as simple “cases” to which one’s antecedently assumed rules apply. This, roughly, is one of the main critiques of principled ethics from the particularist point of view—that we too often substitute rules for reflection; that our rules can in fact limit what we see as morally problematic and morally relevant—that they can, in effect, lead to an immoral ignorance of the fine structure of difficult moral situations.

More to the point still is the fact that emotions are conveyed in ways that are not easily captured in the adherence to rules. There are different ways one can follow a rule—one can do so out of a sense of obligation, or out of fear; one can do so with an understanding of the importance of the rule or without it—with sympathy or without a drop of it. The doctors who performed tests on me as I worried about my children violated no rules that I know of. And yet, when one physician’s assistant kept asking me if I was a drug user—presumably worried that I had come into the emergency room only to get my greedy little hands on some narcotics—my anxiety only increased. In the more serious case I mentioned above—when a family was told they would almost certainly lose a loved one—the absence of sympathy added to the anxiety and isolation of the traumatic event itself. Telling a doctor to say “you have my sympathies,” I hope it is obvious, will accomplish nothing. If the doctor does not mean it—if his demeanor gives the lie to his sympathy—the assertion itself will likely do more harm than good.

At the core of my account of emotional perception is the idea that we display and perceive emotions in one another effortlessly. There is no rule book for being sympathetic—there is no sure-fire way to convey one’s sympathy. Nevertheless, more often than not we know—our bodies know, I would say—the emotions in those around us. They infect us, and we respond to them even before we are consciously aware of them. This means that our emotional lives themselves inevitably create the key in which our actions occur—and hence that there cannot be a rigid distinction between action and attitude.

I have thus far not addressed several key practical issues. While I do not have the space to give these issues anything remotely close to adequate treatment here, I feel obligated to at least touch on two of the more pressing issues. The issue that looms largest, perhaps, is simply the question of training: How do we train health care professionals? A second question—one which is equally important—involves the consequences of taking seriously the moral demand for sympathy. Are we to fire those professionals who are incapable of sympathetic perception—for whom training proves ineffective?

Perception, we have noted, can be trained. The model for this need be no different in health care than it is in other domains: when we train people to “sex” chickens (to perceive the sex of chickens from birth, and at a glance), we do this through repeated trial and error with an expert. The novice spends time with the talented chicken-sexer and practices. Rules cannot replace the simple (guided) repetition of trial and error. As the novice continues to interact with the expert, repeatedly working to achieve the desired result (determining the sex of each new chicken), the novice gradually comes to shape her perception in such a way that success becomes more and more common. Perceiving sympathetically might well be achieved in much the same manner: health care professionals might shadow a mentor who has a proven record of sympathetic perception and interaction until the skill of the mentor is acquired by the novice.

What of those who are incapable of perceiving sympathetically? What happens when the training fails? There are certainly gifted surgeons whose gifts do not extend to the arena of relating to patients (one of whom was featured in an example above). Must these unfortunate physicians find new careers?

We regard certain skills as essential to medical practice: a surgeon who does not have a steady hand will have to find another area of medical practice. The question here is one of value: What do we regard as truly essential to competent practice? Must one be able to perceive sympathetically to be an effective surgeon? If we answer in the affirmative, those incapable of such training will indeed be forced to find alternative employment (perhaps in medical research rather than patient-centered practice—or perhaps in another field entirely). But health care professions are not one-size-fits-all. The moral demands of some areas cannot simply be superimposed without consideration of context on other
areas. In some fields, sympathetic perception is absolutely essential; in others, it is less important. (Nursing requires a greater ability to sympathetically perceive one’s patients than, say, phlebotomy.) Moreover, in a context where patients are often cared for by teams of health care professionals, there may well be room for the gifted surgeon who cannot relate to his patients. One solution to the unsympathetic surgeon allows us to keep the surgeon and still meet the demands of sympathetic perception—a solution that might be summed up in the old adage “from each according to his ability.” When there is a team of health care professionals working together, delicate tasks of sympathy can be handled by those members of the medical team equipped to do so—those with the gift of trained sympathetic perception. In this way, we can meet the demands of sympathy without also losing the talents of those who are less skilled at meeting these demands.

The training of sympathetic perception, I have argued, is not going to be accomplished by simply memorizing rules. Like other techne, learning to perceive sympathetically is 90 percent practice and 10 percent work. There are, of course, more effective and less effective ways of practicing. As I have been suggesting, a focus on rule-based medical ethics can obscure an entire realm of moral reality and moral obligation—it can lead us to think of rules when we should be thinking of people. As I have also conceded, this does not mean rules are useless. It does mean, however, that they can’t do the hard work of moral training by themselves—and that we can’t simply approve our ethics codes and then pretend we’ve met the singular challenge of sympathetically encountering a threatened embodiment.

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Endnotes
2. Difficult does not mean impossible.
4. Aristotle acknowledges this elsewhere (in Nicomachean Ethics, for example—in a quote I give below). As has been pointed out to me, Aristotle also allows for a “common sense” that is not reducible to the standard five.
7. See J. L. Mackie, Ethics: Inventing Right and Wrong.

Attributing Moral Agency to a Group: A Summary of Two Arguments
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Background
This paper was first presented at meetings of the Organizational Ethics Affinity Group of the American Society for Bioethics and Humanities (ASBH) in October 2011. It is hardly news that a great deal of the decision-making that goes on within health care institutions, even the most concrete patient-centered decision-making, is significantly shaped by organizational mission, culture, and policy, which are in turn shaped by decisions at the organizational level. All of these impact individual and group conduct in a health care institution in many more ways than organizational charts and hierarchical models can possibly represent. But it is extremely unlikely that organizational mission, culture, and policy and the decisions that shape them impact an institution and those who carry on its work only in ethically neutral ways. So it is important to examine from an ethical perspective both the influence of mission, culture, and policy on decision-making throughout the institution and also the decisions by which organizational mission, culture, and policy are created and supported. The name currently given to this work both within ASBH and by most writers on it is “organizational ethics.” The Organizational Ethics Affinity Group is a sub-group within ASBH composed of members who judge this work to be an important part of ethics work in relation to health care.

Introduction
It is common for people to attribute actions and omissions to groups, especially formal organizations like corporations and health care institutions, and it equally common to make judgments about the moral/ethical rectitude (or not) of the actions of such groups and to attribute other moral qualities to such groups by reason of their actions or other characteristics. In so doing, one implicitly affirms that groups—and not only individual human persons—can act in ways that are morally/ethically significant. A little reflection will suggest that similar attributions are also regularly made about smaller, not-formally structured groups like family groups, friendship groups, etc., including groups as small as two persons. For example, the sentence, “We decided to go to a movie together and we chose such-and-such a movie; and we made a bad (or a good) choice,” sounds like it is describing judgments, choices, and actions made by this twosome as a unit, as a single, unitary decision-maker.

There is a small, but growing literature on this topic of group agency and the correctness of offering judgments about the moral/ethical rectitude of the actions of groups. This short essay summarizes two arguments in favor of attributing actions to groups. For if our frame of reference is doing organizational ethics work in health care, advocating for health care organizations to develop a more explicit and more self-conscious awareness of the ethically significant components of their organizational life seems clearly to involve presupposing that (some, perhaps all) health care organizations can be correctly described (under appropriate conditions) as unitary actors capable of acting ethically or unethically, i.e., that we can, under certain conditions, rightly attribute moral agency to a group.

But there are thinkers who hold that this idea is mistaken, that group agency is a fiction. The position that they defend is that moral agency can be correctly attributed only to individual human persons and that only the actions of individual human persons can be properly judged on the basis of moral/ethical criteria. This position is mistaken in my judgment, and organizational ethicists routinely treat it as mistaken when they go about their work. But in order to support this claim, we must examine the grounds for saying that some groups can in fact be correctly described as unitary actors capable of acting ethically or unethically.

There are also strategic reasons for organizational ethicists to examine this topic and for an ethicist concerned with organizational ethics to be prepared to carefully support the position that moral agency can be properly attributed.
under certain conditions, to a health care organization. For organizational actors often say things that suggest or even entail that their organization is to be viewed only as a complex system of individual decision-makers and not as a group agent with moral responsibilities; and many organizational actors certainly seem to act as if this was the case. So even if there were not important philosophical reasons for going forward with this examination, organizational ethicists will benefit from having an explanation of these reasons ready to hand.

It is important to remember, of course, that not every group is a group agent. Some groups, including some health care organizations, may in fact be no more than complex systems of individual decision-makers. But then another reason for examining the grounds for saying an organization can be a group agent is that, by doing so well, we can identify the characteristics that determine whether a particular organization is a group agent or not. Obviously it is one thing to be advocating that an organization which definitely is a group agent become more explicit and self-conscious about its ethics, but another thing to be advocating for organizational ethics when the relevant organization cannot, at this point in time, be properly described as fulfilling these conditions and therefore being a group agent. In the latter situation, in fact, advocating for organizational ethics should probably be understood as advocating for the organization to become a different kind of organization, i.e., advocating that it do what it needs to do to become a group agent. (This comment assumes that it is better for a group whose mission, culture, and policies heavily impact decision-making within it to become a group agent and function ethically as such. Identifying the reasons for affirming this, however, is beyond the scope of this paper.) In any case the question at hand is this: What are the grounds for affirming of a group of persons that it is a unitary actor capable of acting ethically or unethically, i.e., that it is a group agent?

The Argument from Analogy

Beginning in the 1970s, a number of business ethicists and a few others like myself began to discuss and write about the theme of group agency. One the best known arguments from this group of writers is that of Peter French (French 1979, 1984), who argued that business organizations could be properly described as unitary actors capable of acting ethically or unethically—and therefore could be rightly judged to be acting ethically or, perhaps more importantly, unethically—because it was possible to identify, in business organizations’ ways of doing decision-making, close analogues to the ways in which individual humans make their decisions. The structure of French’s argument is that we are first to identify the characteristics that justify attributing moral agency to individual humans, and then determine whether there are analogues in the decision-making of corporations and similar organizations. While French did not focus on health care organizations, the characteristics of corporate decision-making that he picked out have very close analogues in large health care organizations, and probably in most smaller ones as well.

The focus of French’s argument—and of most others discussing group agency at the time—was specifically on formally structured groups within which it is ordinarily fairly easy to identify the structures (typically hierarchically organized) by which the activities of decision-making in the group are carried out.1

Among these activities are fact-finding, the identification of alternative courses of possible action, and their evaluation and comparison in terms of identified standards (values, principles, etc.) as these activities are carried out by the persons occupying various offices and roles within the group. In addition, formally structured groups like corporations and health care organizations have explicit rules that determine what acts of the persons in what roles are to be counted as final judgments about what ought to be done and the final choice that the organization is going to act in a certain way—that is, as the decisions—of the organization as such. French labeled these systems of organizational decision-making a formal organization’s “Corporation’s Internal Decision-structure,” its CID.

French’s conclusion, then, was that, because we can identify the same kinds of elements of decision-making in formal organizations that are the basis of our attributing moral agency to individual humans, we are justified in attributing moral agency to organizations of this sort as well (provided we can in fact identify an sufficiently coherent CID in its decision-making activities).

I call this kind of argument for the correctness of the notion of group agency, which French and other thinkers began offering in the 1970s, the argument by analogy. Its approach is nicely summarized in a 1983 article entitled “The Concept of Corporate Responsibility” by the business ethicist, Kenneth Goodpaster, who calls it “moral projection.”

It is appropriate not only to describe organizations (and their characteristics) by analogy with individuals, it is also appropriate normatively to look for and foster moral attributes in organizations by analogy with those we look for and foster in individuals . . . . Put in simplest terms, the principle of moral projection says that we can and should expect no more and no less of our institutions (taken as moral units) than we expect of ourselves (as individuals). (Goodpaster 1983, 10)

I do not see any methodological problem with the argument by analogy. To be sure, the typical description of individual human decision-making that it works with needs to be developed more fully and actual corporate decision-making is more complex than simplistic hierarchical models suggest (King 2010). Consequently, those who support this argument for group agency will need to offer a much more careful correlation of group decision-making activities with the decision-making activities of individual humans as the prime instances of moral agency. Nevertheless, I think this kind of argument will always be an essential part of arguments for the legitimacy of the notion of group agency. But there is another argument that we need to look at, which I find implicit in the work of the British philosopher of law, H.L.A. Hart, and which has been further developed in the work of the philosopher Margaret Gilbert and several other contemporary scholars.2 None of these scholars, however, has focused their attention on health care organizations; and the health care ethicists who have worked in organizational ethics have not focused closely on their presuppositions about group agency.

The Unexplained Remainder Argument

Suppose you are at a professional conference, and you and a friend have decided to go for a drink together this evening or to jog together tomorrow morning. Let us examine this simple example of a group that might be a group agent (and that, if fact, seems unlikely to have a formal CID of the sort French looked for.)

Suppose you show up at the appointed time for the drink or ready to jog, but the other party does not show. In that situation, you might be peeved, upset, even angry; but in any case, setting the emotional content of the moment aside, you would be justified, in the ordinary case, in judging that the other party had failed to do something that they ought to have done. Why? How would you justify to a third party your critical normative response to the other’s not being there? In the ordinary case, we would explain our negative judgment about their conduct by saying, “We had an agreement.” “We made
a plan,” or something like that. Of course, you might instead begin thinking of legitimate excuses that would explain the other party’s absence; but excuses are only relevant if there is something to excuse.

There is now “something”—something that has happened between the two of you—such that non-conformity to this “something” either needs to be legitimately excused or is of itself a sufficient reason for a negative normative judgment about the other’s not following through. This “something” did not exist prior to the two of you “creating it,” so to speak; and once the two of you “created” it, it was something that could justify a critical judgment on your part, and potentially actual criticism, for non-conformity unless there was a legitimate excuse. What we call or should call this “something”—a plan or a shared intention, an agreement or a commitment or a promise, a socially accepted standard of conduct, or whatever—is a topic that I will not address here. The point for present purposes is that this “something” came into existence because the two of you, acting together, created it. It could not have been created by either of you alone, even if each of you had been trying to create it at the same time as the other and with clear knowledge that the other was trying to create it at the same time. For what was created—the plan, the standard for judging future conduct acceptable or not—was, in its being created, the work of both of you together.

That, by the way, is why we explain the legitimacy of our criticism or of our search for excusing conditions by saying, “We had a plan, an agreement, a whatever.” That is why the proper word to name the agent of this plan, or whatever we choose to call it, is “We.”

By way of contrast consider a second possible explanation of what happened when you and your friend decided to go for a drink or to jog together. Suppose that what has happened when the two of you were doing your planning is that each of you decided independently to do this, to have a drink at a certain time and place, to jog with the other party, etc., and that each of you came to this decision in part because of your belief that the other party was deciding to do the same thing—have a drink together, go jogging with you, etc.—and also because of your belief that the other party is deciding to do this with you in part because of his or her belief that you were also deciding to do it and deciding in part because of your belief regarding his or her decision and beliefs about your deciding . . . and so on.

You can, I assume, see where this description is going. A detailed account of such coordinated decision-making by independently acting individuals is carefully worked out in David Lewis’s book, Conventions (1969).

Of course, it is not inappropriate to use the word “we” in describing this second situation; “we” can quite correctly refer to you and I by reason of our acting similarly or our being in the same time or place. But if you show up and the other party does not following the decision-making of the second scenario, then, as Lewis explains, your criticism of the other must needs be that he or she did not do what he or she decided to do. And there is a kind of legitimate criticism that we can offer of another person who has not carried out his or her announced decision about something. But this is not the same thing as the criticism in the first scenario, which I suggest is precisely how we ordinarily understand such situations. And if, instead of a negative normative judgment about the other’s failure to show up, we look for excusing conditions in that first scenario, as we often do, note that it makes no sense for you to look for excusing conditions about the other’s conduct in the second scenario for there is nothing for you to excuse.

Of course, in the second scenario, we might begin to look for causal explanations for what has happened to the other party—physiological, psychological, neurochemical explanations or whatever. But in the second scenario these are not excusing conditions because no negative normative judgment that has anything to do with you is justified if all that was happening is that each of you was deciding independently to act in a certain way.

So what happened in the first scenario was, in other words, significantly different from what happened in the second scenario, and it does not seem unreasonable to speak of this difference by saying that the decision-making in first scenario involved something more than the decision-making in the second.

That is, there is a second kind of argument in favor of the correctness of the idea of group agency; namely, that, for certain actions by groups, when we try to describe them solely in terms of decisions by individual human persons choosing independently, we find that, no matter how sophisticated their efforts to coordinate their individual decisions on the basis of beliefs about each other’s decision-making, nevertheless there is an unexplained remainder that cannot be described solely in terms of individual agency. I call this kind of argument for the correctness of the idea of group agency the unexplained remainder argument. It argues, as I have indicated, that there is something more in these kinds of decision-making by a plurality of agents, something more than the activities—even the closely coordinated activities—of the individual actors (though these are necessary as well). And it proposes that this “something more” has precisely to do with unitary character of the decision, that it is one decision—i.e., one decision by the two parties acting together as a single actor.

It must be admitted, however, that this argument by itself can only demonstrate that there is a crucial difference between two kinds of decision-making by a group. It does not, by itself, demonstrate that what this crucial difference is, i.e., that the “something more” is precisely group agency, even though this is what I am proposing here. But I believe we can reasonably put these two arguments together, especially if we have expanded our description of individual human decision-making and of decision-making by a group, as I suggested earlier. And if we also expand our analogical thinking so that we are not looking only at formally structured groups, but at informally constituted groups of many sizes as well. If we were to carry out this task carefully—which Margaret Gilbert and some other contemporary philosophers, and also a couple of my own graduate students, have begun to do—then, I submit, a very strong case will be able to be made for identifying the unexplained remainder with exactly what the argument from analogy claims is present in such situations; namely, group agency.

In this way, I believe, our commonsense attribution of group agency to groups of many kinds, from pairs and threesomes of friends going for a drink to whole national societies, and to the mid-range groups like the health care organizations bioethicists work with and the professional associations we belong to and that publish newsletters like this one, will have philosophical support for what is currently so widely implied, but only presupposed. We are, I think, still some distance from that goal, and up till now there have not been a lot of philosophers or bioethicists who are concerned to strive for it. I welcome your comments and I would urge you to join in the effort.

Endnotes
1. The organizational theorist W. Richard Scott defines formalization as the “extent to which roles and relationships are specified independently of personal characteristics of the occupants of the positions. [Thus formalization . . . includes] job definitions, procedures, and authority structure” (Scott 1987, 243-44).


References


Conscientious Objection in Health Care: An Ethical Analysis


Reviewed by Kimberley Brownlee

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In this concise and clearly written volume, Mark Wicclair examines the moral contours of conscientious objection in medicine, nursing, and pharmacy. Taking the U.S. health care system as his focus, he highlights the fact that similar ethical questions arise within these three interrelated fields. Those questions include: 1) What is the difference between conscience-based refusals and other refusals of performance? 2) What are the ethical grounds for accommodating the former (and not the latter)? and 3) What are the limits of the exemptions from performance that health care providers can legitimately demand?

Wicclair’s discussion takes up each of these questions in turn with an eye to outlining general ethical guidelines applicable to all three fields of medicine, nursing, and pharmacy. He advocates a compromise position similar to that defended by Dan Brock and others, which accommodates conscience-based refusals within the limits of specified ethical constraints. This middle-way approach contrasts with two extreme positions. The first extreme is “conscience absolutism,” which says that health care providers should be exempt from any act that is contrary to their conscientious beliefs. The other extreme is the “incompatibility thesis,” which says that it is contrary to providers’ professional obligations to refuse to provide any legal good or service within the scope of their professional competence. Wicclair explores several accounts of professional obligation to show, first, that most, if not all, of these accounts are in tension with conscience absolutism; second, that none of them unequivocally supports the incompatibility thesis; and third, that most, if not all, of them favor his compromise approach. Wicclair concludes his book with an analysis of so-called “conscience clauses” in current U.S. law, arguing that in some respects they do too much to protect providers who object and in other respects they do too little. They do too little because they protect only conscience-based refusals and do not accommodate health care professionals who believe that they have a conscience-based obligation to provide a good or service that is prohibited by legal or institutional rules (Chapter 6).

Wicclair’s book is a timely and engaging work that will be a useful reference for health care providers and administrators who must struggle with on-the-ground ethical questions about health care provision. It will also be useful to students and scholars seeking to get a grip on the normative debates about conscientious objection in health care. In this brief review, I examine Wicclair’s treatment of the three questions numbered above and offer a few critical comments along the way. Let me begin with conceptual matters, as it is in this area that I have my most critical comments to make.

I.

The two questions that form the focus of Wicclair’s opening chapter are: What is conscience? and What distinguishes conscience-based refusals from other refusals? Wicclair begins with a helpful overview of competing conceptions of conscience. These include: 1) epistemic accounts that conceive of conscience as a source of moral knowledge and find their roots in Christian thinking that conscience is the voice of God; 2) broadly subjectivist accounts, such as Martha Nussbaum’s, that see conscience as the capacity for moral choice (be it good or bad); 3) cultural-relativist accounts that see it as the internalization of whatever social norms happen to be prevalent in our society; and, 4) more concrete subjectivist accounts that see it in terms of self-consistency and the disposition both to have certain emotional responses and to act in accordance with our ethical beliefs, whatever they may be.

Wicclair does not analyze these competing conceptions, and ultimately tries to sidestep conceptual debates about conscience. He says that, fortunately for the purposes of an ethical analysis of conscientious objection in health care, it is not necessary to address, let alone resolve, any of the thorny ontological and epistemological questions about conscience. “Such questions can be avoided by shifting the focus of conceptual analysis from characteristics of conscience to characteristics of conscience-based refusals…” (4). Wicclair makes this shift by observing that all of the conceptions of conscience he mentions incorporate the notion that “matters of conscience involve a particularly important subset of an agent’s ethical or religious beliefs—core moral beliefs.” And, this idea of core moral beliefs will be his reference for what makes something a conscience-based refusal.

Wicclair’s focus-shifting move is problematic for several reasons. Here are four of them.

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First, although he may be right that all conceptions of conscience include the notion of core moral beliefs, he is mistaken to think that focusing upon that notion enables him to sidestep the thorny conceptual labyrinth of conscience. Saying that we can focus upon core moral beliefs because all conceptions of conscience include such a notion is like saying that we can understand what art is by focusing on what art critics write about. We may well get a partial idea of what art is from that, but it’s not central to what art is that it be the object of art critics’ comments. The fact that all conceptions of some thing share a certain notion does not make that notion the core notion of all of those conceptions or indeed of any of them. Wicclair would do better to be upfront about the fact that he has embraced a broadly subjectivist conception of conscience according to which conscience involves seeking to adhere to certain deeply held moral beliefs whatever they may be.

Second, in trying to sidestep the conceptual disputes, Wicclair passes over some interesting conceptual questions about conscientious belief. For instance, to be conscientious, must a belief satisfy minimal standards of intelligibility and internal coherence? One reason to think it must is that minimal intelligibility and coherence are necessary to determine what content a belief has and, hence, whether and how to be accommodating of it. This relates to another question. To be conscientious, must a belief be consistent with either a person’s other professed moral beliefs or her conduct in practice? One reason to think it must is that this offers the best hope of a guarantee that the belief is indeed one to which she is deeply committed, and not simply one that, out of convenience or self-deception, she tells either herself or others that she believes. In short, the formal standards for conscientious belief are higher than Wicclair acknowledges.

Other conceptual questions that Wicclair could helpfully address relate to the religious half of the notion core moral beliefs. Do all religious beliefs count as core moral beliefs, including beliefs about rituals even if the person thinks non-members of her faith do no wrong in not following the rituals? Or do core moral beliefs include only those religious beliefs to which she is deeply attached? If it’s the latter, then does it matter if the beliefs to which she is deeply attached are not core beliefs within the religion? Does it matter for conscientiousness if she is selectively picking and choosing amongst her religion’s beliefs?

Third, Wicclair’s specification of conscience-based refusals in terms of core moral beliefs is conceptually imprecise. He offers no criterion to distinguish core moral beliefs from other beliefs. Nonetheless he assumes that certain beliefs are, by nature, not amongst people’s core moral beliefs. For example, he says that, in nineteenth-century Britain, parents who refused to have their children vaccinated for smallpox were called “conscientious objectors.” But, he says, “In general, parents opposed vaccination because they believed that it was not safe or effective and not because vaccination was incompatible with their ethical or religious beliefs” (14). What this comment implies is that the parents’ beliefs about safety and effectiveness were, by nature, not amongst their core moral beliefs. But, why must that be? Certainly, it’s likely that many, if not all, of those parents did not count safety or effectiveness amongst their core moral beliefs. But Wicclair gives us no substantive reason why, in principle, they could not have done so.

The same point applies to both Wicclair’s claim that refusals based on self-interest are not conscience-based (6), and his claim that refusals based on commitments to professional integrity are not conscience-based (6-7). With regard to the latter, Wicclair gives the example of doctor-assisted suicide in Oregon, Washington, and Montana, the only U.S. states at the time of writing where this procedure is legal. Wicclair says that a health care provider in one of these states might have no personal ethical or religious reservations about doctor-assisted suicide, but nonetheless might refuse to provide the service because she believes there are better options for terminally ill patients.

Although, of course, it’s true that this provider might not view professional integrity as a core part of her personal moral outlook, another provider might view it in exactly that light. For that provider, adhering to her professional code as she interprets it would be a core personal moral commitment and would underlie her refusal to assist in a suicide. Wicclair does not acknowledge this possibility, but also gives us no reason to dismiss it.

Fourth, one implication of the above points is that Wicclair’s notion of conscience-based belief must accommodate all manner of opprobrious moral beliefs. In conceptual terms, this is unproblematic since Wicclair may conceive of conscience-based belief as he wishes. But, in evaluative terms, this is problematic for his claim that subjective moral integrity is intrinsically valuable. Briefly, Wicclair identifies a connection between the exercise of conscience and the presence of moral integrity. He defines moral integrity as: 1) a set of core moral (i.e., ethical and religious) beliefs and 2) a disposition to act in accordance with those core beliefs. He argues that

from the perspective of the conscientious objector, moral integrity can be an essential component of her conception of a good or meaningful life. In this respect, moral integrity has intrinsic worth or value to the objector. (26)

Additionally, he suggests that, when a failure to accommodate a person’s core moral beliefs causes her to lose her moral integrity (i.e., consistency), this can cause a general decline in her moral character, which is particularly undesirable in the case of health care providers. Finally, he suggests, much more strongly, that, in general, subjective moral integrity actually has intrinsic value, independent of the objector’s perspective. He says that having core moral beliefs associated with one’s self-conception and a disposition to act in accordance with them are intrinsically valuable things worthy of respect. He says that the world is arguably a better place if people have such characteristics than if they do not. Moreover, he says, our admiration for moral consistency, like our admiration for courage and honesty, is at least partly independent of our giving a favorable assessment to a person’s ends and means (27).

All of this is contentious. For one thing, arguably the world would be a better place if people were couch potatoes with no deeply held moral beliefs than if they were universally and relentlessly genocidal toward each other. For another thing, the point about decline of moral character isn’t troubling if the person’s moral starting point is low. If a person’s core moral beliefs are disgusting, a forced loss of consistency is problematic only to the extent that it poses threats to others. For a final thing, on admiration, it’s true that we tend to be highly responsive to their testimony about why we too should have the commitments they have. And, we tend to rely upon their testimony to gain confidence in things we have not experienced ourselves. But, these psychological facts should make us cautious of our admiration as an irrational tendency. We like the comfort of consistency and predictability. We also like to rely upon the false hope of a reliable epistemic division of labor, which we get from a person’s unshakable confidence in something. These are not good reasons to admire consistency. In sum, our unreflective awe of conviction can lead us astray.
II.
Let me now turn to the two evaluative questions noted at the outset. Wicclair’s evaluative project is to examine critically the merits of the two extreme positions of conscience absolutism and the incompatibility thesis, and to endorse a middle-way compromise position that provides limited, context sensitive accommodation for conscientious objection in health care.

In Chapter 2, Wicclair examines these three contending positions in relation to various accounts of professional obligation. He discusses accounts based upon general ethical theories, such as contractarianism, rights-based theories, consequentialism, and an ethics of care. He discusses accounts that track the supposed internal morality of medicine, nursing, and pharmacy, such as essentialist accounts of what it is to be a doctor, nurse, or pharmacist, evolutionary non-essentialist accounts, and traditionalist non-essentialist accounts. And, he discusses contractual obligations and covenant obligations. In relation to all of these accounts, Wicclair argues credibly that the context-sensitive compromise position is more compelling than either of the extremes.

Along the way, Wicclair draws upon a wealth of legal and political material including U.S. legislation, professional codes, public statements, and court judgements. This material is highly informative. He also offers the reader a useful overview of some of the literature in this area as well as an engaging summary of the development of U.S. and U.K. law on conscientious objection in health care.

In Chapter 3, Wicclair develops his positive defense of the compromise position, outlining the “suitable ethical constraints” that rein in conscience-based objections. He distinguishes between two types of conscience-based objections. The first type is refusals to provide a certain good or service, such as euthanasia. The second type is refusals to provide goods and services to a certain group of patients, such as African Americans, Muslims, lesbian women, gay men, unmarried women, etc. A third type of refusal, which Wicclair does not discuss, is, I take it, formal or circumstantial refusals to provide services under certain conditions, such as on certain days or in certain facilities, such as in those facilities that provide services that the provider opposes.

This taxonomy of types of refusals is useful, but draws some overly sharp distinctions. Where do abortion and emergency contraception fit in this taxonomy? Wicclair puts them under the first type. But, are providers who refuse to perform abortions simply refusing to provide a certain service or are they in fact engaging in invidious discrimination against women? As feminist theorists will point out, it is no accident that much conscientious objection in health care arises in areas that closely affect women, such as reproductive choice and pregnancy.

Wicclair identifies certain constraints upon refusals of either of his two types. Many of these constraints are commonsensical. Conscientious objections carry little moral weight if they are based upon demonstrably false clinical facts or are undoubtedly incompatible with the (morally defensible) goals of the provider’s profession, or are based upon invidious discrimination. It would be interesting to know what Wicclair would say about objections that are not based upon unjustifiable prejudice or bias, but instead follow a non-invidious principle of discrimination. Suppose a provider has a deep moral belief that she cannot treat patients on Wednesdays and Thursdays, or a belief that she cannot treat every thirteenth patient she sees. Wicclair might say that the first refusal could have moral merit if it has the pedigree of an established religious faith. (This raises interesting questions about the relative deference we show to religious beliefs over non-religious ethical beliefs.

A non-religious person would have difficulty asserting a deep ethical belief against working two weekdays out of five.) And, Wicclair might say that the second refusal to treat every thirteenth patient does not have moral merit. But, it’s unclear what the grounds would be for saying so if this belief also has the pedigree of an established religious faith.

Wicclair goes on to identify other constraints upon conscientious objection, such as placing excessive harms or burdens upon the patient and obstructing the provision of legally and professionally authorized care.

In Chapters 4 and 5, Wicclair extends his effort to bring medicine, nursing, and pharmacy within a single practically oriented ethical analysis. In Chapter 4, he considers whether health care institutions, and not just individual providers, can assert conscience-based objections. Staying true to his context-sensitive compromise position, Wicclair argues that sometimes some institutions can assert conscience-based refusals. In Chapter 5, Wicclair considers the ethical issues that confront students as a distinct, morally important category of health care providers. This is a key topic to which too little attention is given in many domains. The domain of academic freedom is another example. There is considerable debate about the scope of any special rights that academics enjoy, but little or no discussion of the rights of the politically and legally more vulnerable group that are undergraduate and graduate students. And, finally, in Chapter 6, Wicclair examines the merits and demerits of various conscience clauses, noting the problems with those clauses that do not explicitly prohibit refusals based on invidious discrimination and the problems with those clauses that make no space for providers to insist on providing care where the law or their code forbids it.

The points I have discussed touch on the issues that are, perhaps, of greatest interest to a philosopher. A reader can profit from exploring these conceptual and analytic issues, but a reader can also profit from reading Wicclair’s overview of the legal and historical developments in conscientious objection in health care, his examination of practical constraints, and his reflections upon under-examined groups such as institutions and students. In short, there are many ideas of both philosophical and practical value in Wicclair’s book. In particular, it is a work that will help health care providers, administrators, and students to form a reasonable perspective on the pressing practical ethical problems that they confront every day.

Acknowledgement
I am grateful to Avery Kolers for helpful comments on this review.

Endnotes
1. Wicclair is a touch untidy in his specification of what counts as conscientious objection. In the opening chapters of the book, he says that “acts of conscientious objection involve a refusal to provide a good or service” (10; 5-6; 32). But, in the final chapter of the book, he holds, correctly I believe, that conscientious objection includes not just refusals of performance, but also defiant provision of performance.

The Immortal Life of Henrietta Lacks
Rebecca Skloot (New York: Crown, 2010).
Reviewed by Felicia Nimue Ackerman
Brown University
A cancer patient dies on a colored ward at Johns Hopkins Hospital in the segregated South of 1951. Before her death but without her knowledge, samples of her malignant cells are taken for use in research. These cells turn out to be a
gold mine both scientifically and financially—but not for the patient’s family, whose members are not told about the situation and who often cannot afford the medical care they need. Her daughter, although poorly educated, is smart and vibrant. Finding out about the fate of her mother’s cells makes her eager to learn about cancer and medical research. It also makes her angry.

Add that the mother is so terrific-looking that her photograph (in a flirtatious pose with her hands on her hips and a delightful smile on her face) on a book cover is bound to attract browsers even if they have no idea what the book is about.

Put these ingredients together, and you get a book destined for glory: *The Immortal Life of Henrietta Lacks*, winner of many prizes and citations for excellence. Also a huge commercial success, the book has spent well over a year on *The New York Times* combined print and e-book nonfiction best-seller list, and an HBO movie is in the works.

**Diverse Voices**

Yet author Rebecca Skloot gets off to a limp start. She quotes this passage from Elie Wiesel: “We must not see *any* person as an abstraction. Instead, we must see in every person a universe with its own secrets, with its own treasures, with its own sources of anguish, and with some measure of triumph.” (Italics in original.) Skloot seems unaware that Wiesel’s first sentence is hackneyed and his second is overstated—unless we must see in Hitler a universe with its own treasures.

Fortunately, Skloot is a much livelier writer than Wiesel. Moreover, she prefaces her book not only with Wiesel’s pomposity but also with “Deborah’s Voice,” where Henrietta Lacks’s daughter speaks for herself. Here is part of what Deborah Lacks (who was less than two years old when her mother died) has to say:

> But I always have thought it was strange, if our mother cells done so much for medicine, how come her family can’t afford to see no doctors? Don’t make no sense. People got rich off my mother without us even knowin’ about them takin’ her cells, now we don’t get a dime. I used to get so mad about that to where it made me sick and I had to take pills. But I don’t got it in me no more to fight. I just want to know who my mother was. (9)

Isn’t that more compelling than Elie Wiesel’s ponderous platitudes?

**Ethical Issues in the Use of Human Tissues**

Many readers of this *Newsletter* will have heard of HeLa cells, taken from Henrietta Lacks, which, as the hardcover book jacket notes, “were vital for developing the polio vaccine; uncovered secrets of cancer, viruses, and the atom bomb’s effects; helped lead to important advances like in vitro fertilization, cloning, and gene mapping; and have been bought and sold by the billions.” Skloot provides a riveting account of the story connected with these cells. Equally riveting is Skloot’s account of her own journey in pursuit of the story, a journey involving pursuit of the varied and spirited Lacks family.

Bioethical issues pervade Skloot’s book. For example, who should own tissue that has been excised from patients’ bodies? Who, if anyone, should be able to make a profit from a patient’s excised tissues? Second, should America treat health care as a commodity to be bought and sold, even if that makes it unavailable to some people? Saying that the Lacks family should have gained financially from HeLa cells would not require answering yes to the second question. Maybe profits from HeLa cells should have enabled the Lacks family to escape poverty. But if health care is a human right, you should not have to escape poverty in order to get it.

You should also not have to prove that you deserve health care because of your (or your family’s) contributions to society.

Skloot quotes David Korn, then vice provost for research at Harvard, who says, “I think people are morally obligated to allow their bits and pieces to be used to advance knowledge to help others. Since everybody benefits, everybody can accept the small risks of having their tissue scraps used in research” (321).

However, as Skloot points out on her website, “not everyone does benefit in the United States, because we don’t have universal access to health care. There is an imbalance in this country, which means many of the medical advances coming from tissue research *aren’t* available to everyone, sometimes including those who provided raw materials for the research.” (Italics in original.)

It is reasonable to deny that “people are morally obligated to allow their bits and pieces to be used” without payment if they will not have access to the medical advances that may result. But it is far from obvious that universal access to health care would make it unethical for people to demand payment for the use of their tissues, especially if biotech companies are making a profit from such use. In the book, Skloot says, “Experts . . . worry that compensating patients would lead to profit-seekers inhibiting science by insisting on unrealistic financial agreements or demanding money for tissues used in noncommercial or nonprofit research” (323). But, she adds, “Lori Andrews, who has worked pro bono on all of the important biological ownership cases to date . . . says that many [profit-seeking] scientists have interfered with science in precisely the way the courts always worried tissue donors might do,” which “slow[s] down research because people . . . withhold access for money” (324).

Moreover, commercialization is hardly the only ethical issue involved in tissue research. Skloot points out that “storing tissues from diagnostic procedures . . . and using them in future research doesn’t [legally] require . . . [patients’] consent,” although “[m]ost institutions still choose to get permission” (318). She argues that “[f]or most people, knowing if and how

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**— Philosophy and Medicine —**

Researchers? Corporations? The individuals from whom the tissue comes?

Skloot offers a balanced and lucid treatment of these questions, but many ethical issues connected with her book cry out for much more than she offers in the way of philosophical discussion.

For example, Deborah Lacks’s remarks suggest two logically independent reasons why the Lacks family should be able to get medical care. One reason is that the family (whose members, afflicted with myriad medical problems, have gone through “stretches with no [insurance] coverage or money for treatment” [169]) should share in the financial windfall from HeLa cells, which would enable the family members to afford medical care. Another reason is that the Lacks family deserves medical care as a reward for the benefits that HeLa cells brought to medicine.

Both these reasons are problematic.

When considering Deborah Lacks’ remarks, we should distinguish two questions. First is the one I have already mentioned: Who, if anyone, should be able to make a profit from a patient’s excised tissues? Second, should America treat health care as a commodity to be bought and sold, even if that makes it unavailable to some people? Saying that the Lacks family should have gained financially from HeLa cells would not require answering yes to the second question. Maybe profits from HeLa cells should have enabled the Lacks family to escape poverty. But if health care is a human right, you should not have to escape poverty in order to get it.

You should also not have to prove that you deserve health care because of your (or your family’s) contributions to society.

Skloot quotes David Korn, then vice provost for research at Harvard, who says, “I think people are morally obligated to allow their bits and pieces to be used to advance knowledge to help others. Since everybody benefits, everybody can accept the small risks of having their tissue scraps used in research” (321).

However, as Skloot points out on her website, “not everyone does benefit in the United States, because we don’t have universal access to health care. There is an imbalance in this country, which means many of the medical advances coming from tissue research *aren’t* available to everyone, sometimes including those who provided raw materials for the research.” (Italics in original.)

It is reasonable to deny that “people are morally obligated to allow their bits and pieces to be used” without payment if they will not have access to the medical advances that may result. But it is far from obvious that universal access to health care would make it unethical for people to demand payment for the use of their tissues, especially if biotech companies are making a profit from such use. In the book, Skloot says, “Experts . . . worry that compensating patients would lead to profit-seekers inhibiting science by insisting on unrealistic financial agreements or demanding money for tissues used in noncommercial or nonprofit research” (323). But, she adds, “Lori Andrews, who has worked pro bono on all of the important biological ownership cases to date . . . says that many [profit-seeking] scientists have interfered with science in precisely the way the courts always worried tissue donors might do,” which “slow[s] down research because people . . . withhold access for money” (324).

Moreover, commercialization is hardly the only ethical issue involved in tissue research. Skloot points out that “storing tissues from diagnostic procedures . . . and using them in future research doesn’t [legally] require . . . [patients’] consent,” although “[m]ost institutions still choose to get permission” (318). She argues that “[f]or most people, knowing if and how

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**— Philosophy and Medicine —**

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their tissues are being used in research is a far bigger issue than profiling from them” (317) and adds that “some tissue-rights activists believe that donors should have the right to say…that they don’t want their tissues used for research…that might run contrary to their beliefs” (318).

Here, too, Skloot’s discussion is clear and balanced, but the vast tangle of bioethical issues needs a much deeper discussion than she offers—or, of course, than I can offer in this review.

Additional Ethical Issues

Another area needing further scrutiny is Skloot’s own conduct. Commendably, Skloot “did not want to profit from the Lacks family without giving something in return.” When Deborah Lacks “demanded to know who was paying me to write my book, and how much I was going to give her,” Skloot noted that she had not yet sold the book and was financing her research herself, but that if the book got published, she would “set up a scholarship fund for descendants of Henrietta Lacks” (251).

Skloot kept her promise. You can visit the Henrietta Lacks Foundation’s website at http://henriettalacksfoundation.org to learn about the grants that the Foundation has made for medical and emergency expenses as well as educational expenses of members of the Lacks family. The foundation also considers applications from other “needy individuals who have made important contributions to scientific research without personally benefitting from those contributions, particularly those [or descendants of those] used in research without their knowledge or consent.”

Furthermore, Skloot invited Deborah Lacks to accompany her as Skloot did her research for the book. Skloot “began sending her stacks of information I uncovered about her mother—scientific journal articles, photos of the cells, even an occasional novel, poem, or short story based on HeLa” (252), which helped fulfill Deborah Lacks’s longing to “know who my mother was” (9).

So how might Skloot’s conduct be problematic?

For one thing, it is unclear what percentage of her earnings Skloot is donating to the Henrietta Lacks Foundation. (According to a 2011 article in The New York Times, Skloot “contributes some of her royalties and speaking fees to the foundation, though she does not follow any particular formula.”)1

Another possible problem involves the tenacity with which Skloot pursued the decidedly ambivalent Lacks family. Although Deborah Lacks’s initial response to Skloot was, “I think a book would be great!” (52), she soon switched to, “No interviews. You got to go away. My brothers say I should write my own book. But I ain’t a writer… I can’t talk to you no more. Only thing to do is convince the men” (53-54). So Skloot “started calling Deborah, her brothers, and her father daily, but they didn’t answer” (54). When Skloot finally got Deborah Lacks’s father on the telephone, he “snapped” at her, “[L]eave me alone. I had enough a’ you people. Then he hung up” (55).

But Skloot persisted. Although, she admits, “For nearly a year after our first conversation, Deborah refused to talk to me” (232), Skloot left “messages for Deborah every few days, hoping to convince her that if she talked to me, we could learn about Henrietta together” (232). Such dogged persistence may be standard journalistic practice, but standard journalistic practice is no more exempt from ethical scrutiny than standard scientific practice. Had the context been romantic rather than journalistic, Skloot might well have been branded a stalker. Should she be? Or does the outcome provide retroactive justification for her persistence and presumption?

At any rate, we can admire the good work of the Henrietta Lacks Foundation. We can be glad that Skloot has also ensured that Henrietta Lacks’s sons were hired as consultants for the HBO film that will be based on the book, and that, as she reports on her website, “The Lacks family often comes to public events where I speak about the book—sometimes they just sit quietly in the audience and listen, other times they answer questions or give talks themselves. They also travel extensively now giving talks of their own. Without fail audiences greet Henrietta’s family with cheers and standing ovations.”5

The Death of Deborah Lacks: Implications for the Health Care Debate

Tragically, Deborah Lacks is not present at these events. Having previously had a stroke, she died of a heart attack at 59, before the book was published. Deborah Lacks suffered from hypertension and diabetes, diseases that are often manageable with good medical care. Was her death any more tragic because her mother contributed so much to medicine?

No.

I cannot say whether early and consistent medical care would have prevented Deborah Lacks’s early death. But no one should have to die because she cannot afford basic medical care, not the daughter of a great social benefactor and not the daughter of a villain. The death of Deborah Lacks highlights the importance of recognizing that health care should not be treated as a commercial commodity or as a reward for contributions to society. It is a human right.


Endnotes