NEWSLETTER ON PHILOSOPHY AND MEDICINE

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FROM THE EDITORS

The Belmont Report, which articulated the principles for the ethical conduct of biomedical research in the U.S., is one of the most influential documents in the history of American bioethics. To commemorate the 25th anniversary of the Report, the APA Committee on Philosophy and Medicine sponsored a session to assess and evaluate that landmark document at the Eastern Division meeting in New York, December 28, 2005. We are fortunate to include a collection of papers from that session on “Research Ethics on the 25th Anniversary of the Belmont Report” in this issue of the Newsletter.

“Assessing the Belmont Report” by Tom L. Beauchamp reviews the history of the Report and explores six issues that may be seen as problems with the report. Beauchamp discusses the concept of “respect for persons”; the issue of balance between the rights and interests of subjects, the advancement of science, and the interests of society; the emphasis on protection of subjects; concerns over the usefulness of its abstract principles in guiding concrete judgments; the lack of direction in prioritizing principles; whether the Commission relied upon principles or casuistry in its own deliberations. “The Belmont Principle of Justice: An Idea Whose Time Has Come,” by Ruth Macklin, and “Justice in the Belmont Report and the Social Division of Labor,” by Alex John London, both explain why the Report’s discussion of justice needs to be developed and refined. Both authors make strong cases for taking a broader view of justice than what we find articulated in Belmont. For example, their remarks allow us to see that even though the selection of subjects may conform with the Belmont standards, a trial that depletes a community’s medical resources by diverting medical professionals to the conduct of a clinical trial may be unjust for that reason. “Revisiting the Belmont Report: The Ethical Significance of the Distinction between Clinical Research and Medical Care,” by Franklin G. Miller, focuses on a different set of issues. Miller argues that problems emerge from the Report’s inadequate appreciation of the difference between clinical research and medical care and the subsequent ascription of the ethics of medicine to clinical research. This carefully argued paper also explains the confusions that conflating the two activities promotes and the problems that emerge from accepting the therapeutic orientation of research as the model for distinguishing acceptable research projects from projects that should not be allowed. Together, this collection of papers that examine the Belmont Report in light of its history and our developing insight into bioethics constitutes a valuable contribution to the literature of research ethics.

This issue includes several additional treats. One is a narrative account of a physician’s efforts to honor his patients’ end-of-life requests. “Narrative Matters” by David Muller is a poignant and insightful account of persisting problems around the end of life. We also have “This is for My Grandmother,” a poem by Felicia Nimue Ackerman. This issue concludes with two excerpts from Bioethics: A Systematic Approach by Bernard Gert, Charles M. Culver, and the late K. Danner Clouser. This second edition of their work represents the authors’ continued effort to apply Gert’s account of common morality as a foundation for medical ethics. In the first excerpt (from Chapter 5), the authors engage in a critical discussion of “principlism” as presented by Beauchamp and Childress in Principles of Biomedical Ethics. Gert, Culver, and Clouser argue that such an approach is weak since it is not systematic. The authors’ approach is systematic in that it is grounded in common morality and, therein, provides a way of dealing with cases that is not ad hoc. The second excerpt (from Chapter 7) considers the definition of a mental disorder—whether the judgment that a mental disorder exists reflects value-free science, or the beliefs and values of a particular society. The authors suggest that values are involved, but they argue that these values are universal. These samples are intriguing invitations to explore the rest of their new volume.

As always, please continue to send along your announcements, letters, papers, poetry, and stories so that they can be shared, used, and enjoyed by all. Feel free to volunteer a book review. Contributions and queries should be sent to Rosamond at the address below. For ease in communication, please include your phone and fax numbers and email address.

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On Face Time and Face Transplants

David DeGrazia
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Reflecting the geographical diversity of the APA, the Committee on Philosophy and Medicine is fairly spread out around the country. This makes it somewhat difficult to meet in person. Happily, though, five of us—Gary Seay, Mary Rorty, Rosamond Rhodes, Bob Baker, and I—were able to get together over breakfast during the Eastern Division meeting in New York last December. (Lee Brown, Mark Sheldon, and Ben Rich were unable to attend.) While email communication is sufficient for many purposes, I was very grateful for the opportunity for some face time with committee members. Among the themes we discussed were the following.

The Committee’s webpage could use updating and amplification. For example, it contains information gathered from a survey of bioethics programs, but the survey was conducted in 1997. We might conduct another survey through the Newsletter on Philosophy and Medicine, or we might simply provide links to webpages that already have the sorts of information philosopher-bioethicists are likely to find helpful. Additionally, we could provide links to other organizations of interest, such as the American Society for Bioethics and Humanities (ASBH) and the Association for Practical and Professional Ethics (APPE).

Speaking of allied organizations, we began to consider more extensive collaboration with the ASBH. At the recent Eastern Division meeting, we ran a panel on the 25th anniversary of the Belmont Report, which we had also run at the October ASBH meeting in Washington, D.C. We know that there are many scholars who are interested in the topics of our panels but do not attend both APA and ASBH meetings. We may decide to make such panel-sharing between the two organizations a regular affair.

Future panels were also discussed. Some topics—such as enhancement technologies and the genetic testing of children for adult-onset diseases—have been around for a while but are very rich ethically and are continually energized by technological advances. Other topics, such as neuroethics and nanoethics, seem newer. And then there are topics that are truly new. The best example mentioned at our breakfast discussion was face transplants—although I suspect the likely title for such a panel, “Old Problems with a New Face,” would be more interesting than the issues themselves. In the next few months, we will select some philosophically rich themes related to bioethics as topics for upcoming panels. Stay tuned.

Assessing the Belmont Report

Tom L. Beauchamp
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The Belmont Report was published in 1978 by the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research. Its goal was to provide a framework of moral principles that would serve as the backbone of the federal oversight system in the United States, so that meaningful protection was afforded to research subjects. The National Commission published seventeen reports and appendix volumes. Several went directly to the Secretary of the Department of Health, Education, and Welfare (DHEW) and became codified in federal regulations (US 45 CFR 46). The Belmont Report is not itself a regulatory document, only the Commission’s framework of moral principles.

This framework of principles is still today referred to as “the Belmont principles.” The Commission identified three general principles as underlying the conduct of research: “respect for persons,” “beneficence,” and “justice.” The organizing conception in the Report is that respect for persons applies to informed consent, beneficence applies to risk-benefit assessment, and justice applies to the selection of subjects. The principle of respect for persons demands that the choices of autonomous persons not be overridden or otherwise disrespected and that persons who are not adequately autonomous be protected by the consent of an authorized third party likely to appreciate the subject’s circumstance and who will look after his or her best interests. The principle of beneficence is an abstract norm that includes rules such as “do no harm,” “maximize possible benefits and minimize possible harms,” and “balance benefits against risks.” The principle of justice requires fairness in the distribution of both the burdens and the benefits of research.

The Belmont Report makes no pretense to render its principles specific and practical for institutions that conduct research. That objective was to be accomplished by the other sixteen volumes on research ethics. Belmont commissioners and staff were keenly aware that this framework is too indeterminate by itself to decide practice or policy or to resolve moral conflicts.

Despite the wide acceptance of the authority and contribution of this framework for research ethics, several issues have been or can be raised about the adequacy of the Belmont principles. Six possible problems are worthy of discussion still today.

(1) The principles are arguably run together in the way they are expressed, rather than standing as independent principles. The principle of respect for persons is the most suspicious case. It appears to blend two independent principles: a principle of respect for autonomy and a principle of protecting and avoiding the causation of harm to incompetent (nonautonomous) persons. The Commission says that it is attempting to protect both autonomous persons and those with “diminished autonomy,” i.e., those who are incapable of self-determination. Both are persons, it says, and both are entitled to protection. The problem is whether there is any meaningful way to justify protections for persons who are incapable of self-determination except by appeal to the principle of beneficence. If not, then the Commission has adopted an incoherent position in thinking...
that the principle of respect for persons and the principle of beneficence are independent principles.

(2) The Commission was repeatedly concerned that it had become too easy in the biomedical world to use utilitarian justifications of research. The Nazi experiments, Tuskegee, and the Jewish Chronic Disease Hospital cases all seemed to present a very utilitarian view of social beneficence that justified using human subjects on grounds of benefit to the broader public. However, the Commission has been itself accused of having inadequate internal controls in its moral framework to protect subjects against abuse when there was the promise of major benefit for society. For example, the Commission’s report on children has been criticized for an unjustifiable utilitarian justification of research that placed children at undue risk. Whatever the merits of this criticism, the Belmont Report was written, in part, to ensure that we appropriately balance appeals to social utility in the justification of research. That is, a major purpose of the report was to properly balance the rights and interests of subjects with those of science and society. It may, of course, be doubted that the Commission actually did determine how best to control utilitarian balancing, but it is also reasonable to doubt that any general solution to this problem has ever been provided.

(3) The Belmont Report, and the National Commission more generally, can also be criticized for being overly protective of subjects and not utilitarian enough to meet the needs of certain classes of persons. The emphasis of the Commission was on the protection of subjects from research injury. Research participation was conceived as a burden accepted to advance the public good. The notion that research is not always viewed by subjects as burdensome was underexamined. The AIDS epidemic altered this assumption, perhaps forever. Whereas Belmont was protectionist, AIDS activists sought not protection from but inclusion in the research process. They wanted justice and respect for their autonomy, but not along the lines staked out in the Belmont Report. They wanted to be able to choose unapproved drugs. Justice, they thought, should allow them access to clinical trials. Whether this viewpoint constitutes an expansion in the scope and use of the Belmont principles, rather than a confrontation with these principles, remains a vital question still today.

(4) The Belmont Report has also been criticized for its abstractness and inability to resolve or otherwise treat practical moral problems. The Report anticipates this criticism and cautions that its principles cannot always be applied so as to resolve beyond dispute particular ethical problems. The objective is [only] to provide an analytical framework that will guide the resolution of ethical problems arising from research involving human subjects. The Commission is warning readers that they should not expect to be able to use Belmont principles as a checklist of federal regulations or as guidelines like recipes in cooking. Nonetheless, several critics have asked whether these principles are in any meaningful respect practical, or even useful. The concern is that the Belmont principles underdetermine almost all moral judgments because there is too little content in abstract principles to determine concrete judgments. This criticism merits careful attention, but it is also reasonable to ask whether any system of principles, rules, or general guidelines escape this problem. The criticism no doubt holds for unspecified principles, but does it hold for principles that have been well specified for a context? This question too has never been satisfactorily resolved.

(5) The Belmont Report has also been faulted on grounds that it gives no indication of how to prioritize or weigh its principles. Some think that the Commission should have argued that one or more of its principles has priority—for example, that considerations of respect for persons and justice take priority over considerations of social benefit. Critics often support a model of basic moral principles and protections that cannot be violated under any circumstances, even if there is a clear and substantial benefit for society. Such restrictions on or prioritizing of principles are emphatically not envisioned in the Belmont Report. The Commission holds that its principles are more or less weighty depending upon the particular circumstances in which the principles are to be applied—a balancing theory. That is, no principle in the basic analytical framework is allowed to have an ordered priority over any other principle. This is a defensible conception, though little is done to defend it in the report itself.

(6) One former Commissioner, Albert Jonsen, and one staff member, Stephen Toulmin, have questioned whether the National Commission actually used its framework of Belmont principles to support or defend its own bioethical conclusions. They have argued that the Commissioners believed and published as principlists but actually worked as casuists. This thesis is not a criticism of the Commission’s substantive work but, rather, a methodological comment on the use and limits of its principles. These authors hold that the Commission’s actual moral deliberations proceeded more by the consideration of influential cases than by appeal to universal principles. It is probably correct to say that principles were of a lesser importance than readers might suppose when they read the Belmont Report. They are important general guidelines, but overrated ones if revered for their practicality. From this perspective, the Commission should be thought of as using principles primarily as very general guiding ideals that must be substituted by others forms of practical reasoning. Belmont itself does not seem to claim more.

Finally, the Belmont Report is one of the few documents that has influenced almost every sphere of activity in bioethics: moral theory and general standards of research ethics, government regulatory activity, bioethics consultation, and even medical practice. Its influence has arguably been as extensive in practice as in theory. In federal regulatory oversight and law, Belmont has at times assumed a near canonical role as the groundwork of federally funded research. Of course, the Belmont principles found their way into every document the National Commission published, and these became the backbone of federal law governing research involving human subjects.

The legacy of Belmont may be most enduring in areas of practice. Federal regulations require that all institutions receiving federal funds for research espouse a statement of principles for the protection of human subjects. Virtually all such institutions have subscribed to the Belmont principles as the basis of their efforts to assess research protocols. Professional associations too have widely recognized the authority and historical significance of the Belmont principles.

Whatever the influence and enduring legacy of Belmont, it is not clear that scientists who today are involved in research with human subjects are very conversant with the Belmont principles, just as their predecessors a few decades ago lacked a working knowledge of the Nuremberg Code. Even if the National Commission and its Belmont Report succeeded in embedding important principles in the heart of research ethics, its principles may be more revered than understood and practiced.
The Belmont Principle of Justice: An Idea Whose Time Has Come

Ruth Macklin
Albert Einstein College of Medicine

A New York City firefighter learned that he had chronic myelogenous leukemia, a disease with a terrible prognosis and for which there is no cure. But then he enrolled in a research study that was testing an experimental drug manufactured by the giant pharmaceutical company Novartis. The drug worked, is now on the market, and the firefighter is still taking it. The company supplies the drug to him for free because he participated in the clinical trial.1

In contrast, consider the policy of the Eastern Cooperative Oncology Group (known as ECOG), which is one of the largest clinical cancer research organizations in the United States, conducting clinical trials in all types of adult cancers. The organization is funded primarily by the National Cancer Institute. The informed consent document for research studies sponsored by ECOG says: “The drug will be supplied free of charge to you during the trial. However, if the drug becomes approved for marketing while you are still enrolled in the trial, you or your insurance company will have to pay for it.”

What do these two stories have to do with the Belmont Report? The answer is: everything and nothing. They have everything to do with a question about justice, one of the fundamental ethical principles identified in Belmont. That question is: What, if anything, is owed to research subjects when the clinical trial in which they are enrolled is ended? However, the two stories have nothing to do with the principle of justice as articulated in the Belmont Report. Accordingly, the title of this presentation is somewhat misleading. It is true that attention to justice in research is an idea whose time has come. Since Belmont identifies justice as one of the three fundamental principles of research ethics, it marked an important ethical milestone in the research enterprise. Justice in research had rarely, if ever, been discussed prior to Belmont.

The focus of the discussion in the Belmont Report is on distributive justice. The conception of justice that applies to the two stories is more appropriately termed justice as reciprocity. The New York City firefighter not only received a drug that benefited him during a clinical trial; the manufacturer continued to make the drug available to him when the trial was concluded and the drug was on the market. Novartis reciprocated the subject’s participation in the research—from which the company stood to make a huge profit—by providing the medication to him free of charge. In contrast, the Eastern Cooperative Oncology Group informs the cancer patients enrolled in the research it sponsors that not only is there no plan to make a successful product available to them after their participation is concluded, but also, if the drug becomes approved by the FDA while patients are still research subjects participating in the study, they or their insurance company will have to pay for the medication that may still be needed. Not only do they not get the drug free of charge after their participation in the research is concluded, but they may actually have to pay out of pocket for the drug while they are still enrolled as subjects. No reciprocity there.

In explaining what justice requires in the research context, the Belmont Report states that “research should not unduly involve persons from groups unlikely to be among the beneficiaries of subsequent applications of the research.”2 This is a classic statement of distributive justice, the conception that mandates a fair distribution of the benefits and burdens of research. Yet in Belmont, the application of justice is limited to the question of a fair selection of participants. It does not address what is owed to them in the form of post-trial benefits when research is completed. The Belmont conception of justice could be fulfilled in one of two possible ways: either exclude as subjects in research those individuals or groups unlikely to be the beneficiaries of subsequent applications of the research, or else seek to ensure that those individuals or groups that serve as research subjects actually do receive the benefits of future applications.

The Belmont Report was written at a time when participation in research was considered a risky business. Even many years later, Madison Powers repeated that perception in describing the role of justice in the research enterprise. Powers wrote: “The focus on protecting the vulnerable from the imposition of greater health-related risks is precisely the animating concern of the dominant norm of justice in research as protection.”3 Now, however, twenty-five years after Belmont appeared, ethical concerns about justice in research have added two new dimensions. The first is mandating access to clinical trials for groups that had been traditionally under-represented in research (chiefly women and minorities), and the second is attention to the question of what is owed to research subjects after their participation in a drug study has ended.

Justice in Expanding Access to Research

With the emergence of AIDS in the early 1980s and the first clinical trials of experimental medications, the presumption shifted sharply from the need to protect people from research risks to that of an “inclusionist” perspective. Early in the epidemic, AIDS activists in the United States clamored to get into clinical trials and argued forcefully for more research and the opportunity to enroll more people in trials, and the FDA responded with mechanisms to provide expanded access.4 As Beauchamp and Childress wrote: “In the 1970s and early 1980s, the emphasis was on protecting individuals from risks associated with research. Beginning in the 1980s, the emphasis shifted to increasing access to participation in research.”5

An Institute of Medicine study conducted in 1992-1993 noted that “attention has turned away from the problem of unduly subjecting certain groups to disproportionate risks and toward the problem of denying the benefits of research to certain classes of people who have not frequently been the subjects of research.”6

The Institute of Medicine (IOM) study focused on the inclusion of women in research. The published report said that

For the overall biomedical research agenda to comply with the requirements of justice, studies must not only include women as well as men, but also women and men from different age cohorts and different racial and ethnic groups. If clinical studies are intended to benefit the population as a whole, then the systematic exclusion of women from such studies places them at an unfair disadvantage.7

The disadvantage identified by the IOM study on women and health research was the relative absence of research findings on major diseases, such as heart disease, that pertain to specifically to women. The injustice in the case of women and people with HIV/AIDS was the lack of research and the consequent failure to obtain contributions to knowledge that would benefit those groups.

Most recently, the presumption emerged to include children in all clinical research—not limited only to studies that focus on diseases of childhood.8 This latest move, as it turns out, is in direct opposition to what Belmont says about fair selection
of subjects. In the section that addresses the application of the fundamental principles, *Belmont* says: “it can be considered a matter of social justice that there is an order of preference in the selection of classes of subjects (e.g., adults before children).” Here again is a reflection of the dominant perception at that time of research as risky. According to that perception, it is only fair that the less vulnerable (adults) serve as research subjects before the more vulnerable (children).

**Access to Post-trial Benefits of Research**

The twin ethical concerns in any research are an imposition of undue risks or other burdens and the absence of expected benefits. Although risks to subjects remain an enduring worry, the failure to share in the benefits of research when successful products or contributions to knowledge result has only recently been acknowledged as a major ethical concern. However, this concern has been voiced mostly in connection with international research, in particular, in clinical trials sponsored by industrialized countries or industry and conducted in resource-poor countries. Curiously, however, this feature has been largely, if not entirely, ignored in the United States, where a substantial portion of low-income people cannot afford many expensive medications on the market. There is some evidence that such patients enter trials to obtain care and treatment otherwise unavailable to them outside the research context.

Access to post-trial benefits in the form of successful products of research could readily be subsumed under the concept of distributive justice. Since successful products that result from research clearly count as benefits, *Belmont*’s statement of justice in research is applicable: “Who ought to receive the benefits of research and bear its burdens? This is a question of justice, in the sense of ‘fairness in distribution’ or ‘what is deserved’. An injustice occurs when some benefit to which a person is entitled is denied without good reason or when some burden is imposed unduly.” If any benefit is “deserved,” it is that of subjects receiving a medical product they still need after their participation in research has concluded.

An equally appropriate conception of justice is *justice as reciprocity*. In its report on international research, the National Bioethics Advisory Commission (NBAC) describes that conception as follows:

Justice as reciprocity...is concerned with what people deserve as a function of what they have contributed to an enterprise or to society. In the context of clinical trials, justice as reciprocity could mean that something is owed to research participants even after their participation in a trial has ended, because it is only through their acceptance of risk and inconvenience that researchers are able to generate findings necessary to advance knowledge and develop new medical interventions.9

There is nothing in the U.S. Code of Federal regulations governing research that addresses the question of post-trial benefits to research subjects. However, other international guidelines do include such provisions. Probably the best known of these is the *Declaration of Helsinki*. One provision states that “At the conclusion of the study, every patient entered into the study should be assured of access to the best proven prophylactic, diagnostic and therapeutic methods identified by the study.”10 Another strong requirement is found in a guidance document for preventive HIV/AIDS vaccine research: “Any HIV preventive vaccine demonstrated to be safe and effective... should be made available as soon as possible to all participants in the trials in which it was tested.”11

Both of these documents include a statement about post-trial benefits to research subjects that looks very much like an ethical obligation. Yet, since both statements are written in the passive voice, it is not clear on whom that obligation rests. In the case of the New York City firefighter, the company undertook the obligation, fulfilling the requirement of justice as reciprocity. The article that reported the case of the firefighter did not mention whether Novartis made the drug available to all of the research subjects in its clinical trial; presumably, it would be an injustice if some but not all eligible participants were given the drug without charge after the trial ended. The Eastern Cooperative Oncology Group would likely defend its policy by noting that neither it nor the National Cancer Institute operates under a mandate to provide medical services. It would then fall to the manufacturer of whatever product or combination of medications were provided to patients to supply them with a successful product that resulted from the trial.

The *Belmont Report* included what was at the time a pioneering step by identifying justice as one of the fundamental ethical principles for research involving human beings. That it did not go far enough in explicating and applying that principle can be understood and excused. Times change, perceptions change, and the research enterprise has changed. The increased attention to matters of justice in the past quarter century is a form of moral progress; *Belmont* was an early progressive step along that road.

**Endnotes**

7. Ibid.
research ethics. In comparison with the value of respect for autonomy and its corresponding requirement to secure the free and informed consent of research participants, the value of justice and its requirements have received far less philosophical and practical attention in the context of research ethics. For instance, a cursory search of PubMed for articles on justice and medical research yields 533 hits, whereas a search for informed consent and medical research yields 4,324. Similarly, whereas the requirements of informed consent have been clearly elaborated in terms that are operationally useful and action guiding, the requirements of justice tend to be spelled out in fairly general terms as requirements that like cases be treated alike, that processes and outcomes be fair, or that equals be treated equally. After the value of informed consent, the most significant moral attention in research ethics focuses on the requirement that the research present participants with only reasonable risks. In part, this is because there are inherent and long-acknowledged tensions at the heart of the research enterprise between the interests of trial participants and the methods and objectives of scientific research. In this regard there is at least a robust literature on the conflicting obligations of physician-researchers as well as a literature on clinical equipoise that represents a concerted effort to provide operationally useful guidance about when the risks within a particular clinical trial are reasonable.

In contrast to these other values, the elucidation of justice and its requirements in the context of research ethics is in its relative infancy. To a certain degree, this may be due to the fact that unlike respect for persons and beneficence or nonmaleficence, there is a significantly greater diversity to the views of what justice is and what it requires. Similarly, given the scope of justice as a value governing the interactions of different individuals or groups and the operations of various social institutions, the normative force of this value does not emanate from the role-related obligations of any particular profession. When combined with the aspiration of research ethics to function as a practical enterprise that does not get bogged down by the recapitulation of longstanding and divisive theoretical disagreements, something of an agnostic attitude toward the requirements of justice may actually appear to be a virtue of research ethics.2

In the brief discussion that follows, I argue that the desire to focus on what are viewed as more practical or pragmatic concerns and to remain agnostic about controversial issues of social justice has resulted in a lingering parochialism about issues of justice in the research context. I begin, therefore, by illustrating how the avoidance of substantive questions about social justice leads to a parochial approach to issues of justice in the Belmont Report. I then show how this avoidance may be at least partly responsible for the waning influence of some public consensus documents in research ethics. I also suggest that this parochialism may be responsible for generating a practical conflict that may threaten the moral mission of research ethics.

To be clear, there are various reasons for the avoidance of these larger issues in the Belmont Report, and my primary concern is not to impugn the merits of what was without doubt a fundamentally important and forward-looking document in its day. Rather, I am concerned with the Belmont Report insofar as it remains a living document that continues to shape much of the discourse in research ethics and which has not yet been superceded by a comparable moral framework. My criticisms, therefore, are intended to highlight the limitations of the treatment of justice that we find in the Belmont Report in order to underscore the need to broaden the discussion of justice in research ethics.

I conclude by suggesting that the one way to broaden the discussion of justice in research ethics is to begin with a conception of the clinical research enterprise as one social activity that takes place within a broader social division of labor that must be justifiable to the members of the community whose interests it is supposed to serve. Only within such a broader social perspective can we properly consider how our research priorities ought to be determined and evaluated, how the research endeavor should relate to other social institutions such as health care and public health institutions, and which stakeholders in addition to researchers and IRB members have responsibilities to ensure that clinical research is properly responsive to broader issues of social justice.

**Agnosticism about Justice in the Belmont Report**

The Belmont Report begins its discussion of justice by delineating a set of fundamental questions concerning both the scope and application of this value:

[a] Who ought to receive the benefits of research and bear its burdens? This is a question of justice, in the sense of “fairness in distribution” or “what is deserved.” An injustice occurs when some benefit to which a person is entitled is denied without good reason or when some burden is imposed unduly. [b] Another way of conceiving the principle of justice is that equals ought to be treated equally. However, this statement requires explication. Who is equal and who is unequal? What considerations justify departure from equal distribution? (letters in brackets added)

These questions deal with features of justice that are centrally relevant to its application in general and to the institutions and practices of clinical research in particular. After all, there are many different kinds of benefits that attach to the research enterprise at a variety of different levels. In order to know what the value of justice requires in practice we need a sharper sense of which of these benefits are relevant to the question that I have labeled (a) above. Unfortunately, the Belmont Report does not clarify or specify what the distinctive benefits of clinical research are that are to be distributed as a matter of social justice. In fact, the social value of clinical research is taken for granted as a background assumption of the document, and there is no explicit clarification of the nature or source of this social value. This is worrisome, however, not because of skeptical doubts about whether clinical research has genuine social value but because of the many different respects in which clinical research can be seen as having such value. For example, private corporations, civic officials, and even individual research participants may be interested in clinical research as an engine of financial profit. Academic researchers may be interested in clinical research as an engine of scientific discovery. Other research participants may be interested in clinical research as a means of accessing medical care, be it basic care or novel diagnostic of therapeutic modalities.

Similarly, in reference to the issues in (b) above, we are told that, “it is necessary, then, to explain in what respects people should be treated equally.” In other words, the application of justice requires that we define the space of equality with respect to which equally situated individuals can make a claim to receive like treatment. But again, although this issue is centrally relevant to justice, no answer to this question is ever explicitly proposed. We are given, instead, a list of “widely accepted formulations of just ways to distribute burdens and benefits” without being told which of the items on this list are relevant to the research context and in what ways.

The evasion of these issues, however, is not without consequence. After discussing Nazi atrocities and the abuses
at Tuskegee we are given two examples of the way in which “conceptions of justice are relevant to research involving human subjects.” I label these two quotes as passages I and II:

I. The selection of research subjects needs to be scrutinized in order to determine whether some classes (e.g., welfare patients, particular racial and ethnic minorities, or persons confined to institutions) are being systematically selected simply because of their easy availability, their compromised position, or their manipulability, rather than for reasons directly related to the problem being studied.

II. [i] Finally, whenever research supported by public funds leads to the development of therapeutic devices and procedures, justice demands both that these not provide advantages only to those who can afford them and [ii] that such research should not unduly involve persons from groups unlikely to be among the beneficiaries of subsequent applications of the research. (numbers added)

Passage I expresses a claim that is almost axiomatic in research ethics, namely, that research subjects should be selected because of the relevance of their health needs to the research question and not because of their compromised social or economic position. But without answers to the questions outlined in [a] and [b] above, it is not clear what reasons are sufficient to permit the inclusion of vulnerable populations in clinical research. Similar problems arise for the requirement in passage II. In particular, it is not clear how either of the requirements stated there follows from the discussion of justice that precedes it, or from the examples of the abuses of the Nazis or at Tuskegee. This might help to explain why the first of the requirements outlined in II appears to have been largely ignored and why the second has been the subject of heated dispute recently.

An example will help to illustrate how, without clarification of the issues outlined in [a] and [b] above, the requirements in these passages either remain fundamentally ambiguous or appear to be ad hoc pronouncements. Consider a trial of a vaccine for hepatitis A that is proposed for a community in which there is a sizable incidence of that condition but in which finding a treatment for this affliction is not viewed as a leading health priority. Moreover, this is a community that is probably too poor to afford what will likely be a very expensive vaccine. If we assume that the trial meets the other conditions outlined in the Belmont Report, then is having a high incidence of hepatitis A a sufficient reason to include a particular population in that trial? Certainly this would seem sufficient to establish the scientific relevance of the research to the population in question. Now assume further that the research sponsor is willing to work with the host community to ensure that the research provides a variety of economic advantages to members of that community, even though the vaccine itself will not be integrated into their health-care infrastructure. Is such a trial permissible in light of conditions I and II?

According to those who endorse the requirement of reasonable availability, without making the vaccine itself available to members of the host population in the future, the trial would not be ethical. It would violate the principle outlined in II.ii. Proponents of the fair benefits approach, in contrast, have argued that the above scenario is sufficient to permit the conduct of cross-national research in developing countries. Their rationale is simple. If the research has genuine merit, if it is carried out in accordance with the other principles of the Belmont Report, and if the host community stands to benefit from hosting the initiative, then it represents a mutually beneficial collaboration that passes the test of condition I. The requirement in II.ii. is therefore viewed as either unnecessary or misguided.

The issue that divides these two camps hinges fundamentally on the questions outlined in [a] and [b] above. Proponents of reasonable availability are often not clear as to why they accept the requirement of II.ii., but it seems to emanate from the idea that the distinctive benefit that clinical research is capable of producing is the production of new medical interventions and, therefore, that research should not unduly involve persons who will be unlikely to have access to these interventions. It also seems to presuppose that the domain of equality is defined by one’s contribution so that communities that make discoveries possible should share in those specific benefits.

The claim that researchers and their sponsors should endeavor to ensure that the fruits of any successful research initiative will be made reasonably available to members of the host community also seems to be most reasonable when passage I above is interpreted in a particular way. Namely, the reasonable availability requirement seems to presuppose a reading of passage I according to which a research initiative is relevant to the health needs of the study population just in case it targets a health need that constitutes a health priority of the host community. If the study targets a health need that is represented in the host population, but which is not a local health priority, then it seems unreasonable to require various stakeholders to make that intervention available in the host community.

For roughly this reason, the proponents of what is referred to as the Fair Benefits approach think that the above view of the benefits of research is overly restrictive. Clinical research is capable of generating a whole host of benefits of which new medical interventions is only one subset. What is necessary, on their view, is not that the host community receive access to any interventions that might be vindicated in that research, but that the host community receive a package of benefits that it takes to be sufficient to justify participating in the research. Such a package could contain provisions for the host community to receive access to any interventions that are vindicated by the research, but it does not have to. This position, in turn, is consistent with a view of clinical research primarily as an economic engine, broadly construed, and with a view of equality within which bargains are fair just in case they are mutually beneficial and the benefits are distributed to the various parties in proportion to their respective bargaining power.

This position also presupposes a more permissive reading of the requirement in I above. On this reading, research is determined to be relevant to the health needs of the host population just in case it targets a condition that is sufficiently represented in that population as to make a scientifically valid study feasible and the host community receives a package of ancillary benefits that it regards as making research participation worthwhile.

Because the Belmont Report leaves the issues outlined in [a] and [b] unresolved, and because the dispute between the proponents of the reasonable availability requirement and the proponents of the Fair Benefits approach appears to hinge on precisely these issues, the Belmont Report will be of little use in the effort to bring a reasoned resolution to such debates. Each side is able to couch their arguments in terms that can be found within the report, and where their views diverge from the report’s practical recommendations they can pit substantive arguments about the issues in [a] and [b] against what then look like arbitrary pronouncements of the National Commission.
In this regard, the Belmont Report is not alone. Roughly the same gambit is playing out relative to a number of important international declarations or guidelines concerning human subjects research.* This analysis of the Belmont Report is simply meant to clarify why the relevance of these documents appears to be increasingly questioned by underscoring one of the argumentative strategies that exploits their common agnosticism about substantive matters of justice.

**Parochialism about Justice in the Belmont Report**

In the previous section I argued that the evasion of important questions about the scope and application of justice exemplifies the respect in which the Belmont Report represents a tendency toward agnosticism about justice in research ethics. Substantive questions of justice are recognized as relevant to the ethical conduct and evaluation of clinical research, but they are left unanalyzed and largely unaddressed. Two factors may help to explain this agnosticism. First, the charge to the National Commission instructed them “to identify the basic ethical principles that should underlie the conduct of biomedical and behavioral research involving human subjects and to develop guidelines which should be followed to assure that such research is conducted in accordance with those principles.” This instruction seems to give the National Commission broad latitude in articulating the fundamental principles that should govern research with human subjects and what these principles require in actual practice. However, the instructions to the Commission also ask them to focus specifically on the distinction between research and practice, guidelines for carrying our risk assessments, informed consent, and delineating “appropriate guidelines for the selection of human subjects for participation in such research.” So the Commission’s ultimate focus on the selection of research subjects as the primary domain for the application of concerns about justice reflects, to some degree, their effort to address the issues they were charged to address.

Because their charge was broad enough to permit a more comprehensive statement about justice in the research context, the Commission’s avoidance of these larger, theoretical issues in favor of a focus on the selection of research subjects may also reflect a desire not to become bogged down in traditional philosophical disputes about abstract theoretical issues. One of the hallmarks of bioethics as a discipline, and research ethics in particular, has been a desire to achieve practical results that are informed by philosophical reflection, without becoming stymied or mired in disputes over first principles. The selection of research subjects appears to be clearly relevant to concerns about justice and to be something over which both researchers and IRB members have significant control.

These ideas are conveyed in the following passage:

**III.** Thus, even if individual researchers are treating their research subjects fairly, and even if IRBs are taking care to assure that subjects are selected fairly within a particular institution, unjust social patterns may nevertheless appear in the overall distribution of the burdens and benefits of research. Although individual institutions or investigators may not be able to resolve a problem that is pervasive in their social setting, they can consider distributive justice in selecting research subjects.

Even though researchers and their respective institutions may not be able to change broader social injustices, they can take them into account so as to ensure that research does not recapitulate or exacerbate those injustices. As attractive as this very pragmatic idea is, however, it is not clear that these goals can be achieved simply though the prudent selection of research subjects.

At best, the fair selection of research participants can ensure that, for any research endeavor, no subject population is allowed to participate unless the conditions outlined in the rest of the Belmont Report, including those stated in I and II above, are satisfied. Keeping in mind that there are more restrictive and more liberal interpretations of these requirements, the provisions will determine how and when burdened populations are permitted to participate in clinical research. Nevertheless, this focus on the fair selection of research participants only helps to avoid what we might call problems of wrongful participation.

Focusing on the selection of research participants cannot address profound issues of social justice surrounding the selection of research questions, the development of research priorities, and the relationship between these issues and larger patterns of social inequity. It may be true that on a case by case basis, no individual researcher and perhaps no individual sponsoring institution is capable of rectifying longstanding social injustices. But the clinical research enterprise, as a social activity that is capable of generating important information, might have a fundamentally important role to play in helping to rectify certain unjust social patterns over the long term. Moreover, this social activity is funded, facilitated, and carried out by important social institutions whose ultimate social justification, in most cases, lies with their capacity to advance the common good of the community members whose interests they are supposed to serve.

Clearly the consideration of these broader issues is not precluded by the discussion in the Belmont Report. But in mandating that issues of justice focus primarily on the selection of research participants, the Belmont Report frames the central questions of justice in a way that focuses almost exclusively on factors that can be more or less directly influenced by IRBs. However, IRBs typically review research protocols after the key elements of the research question have already been spelled out and central elements of the research design have already been established. The case-by-case perspective of research ethics is itself, therefore, a product of the discipline’s almost exclusive focus on the IRB as the primary context in which the ethical aspects of clinical research are assessed. This case-by-case perspective, in turn, makes the project of addressing broader issues of social justice appear to be infeasible.

Although researchers and IRBs certainly have a crucial role to play in the process of ethical research design, conduct, and oversight, they are not the only stakeholders in this process. In fact, their ability to affect issues related to social and distributive justice are severely limited in comparison with governmental and social institutions. These larger, institutional stakeholders have the capacity to set the incentives that shape the broader research agenda as well as to facilitate the coordination of researchers and other governmental and non-governmental bodies in order to address problems in a multi-dimensional way. Unfortunately, the ethical obligations of these entities that shape the research enterprise long before a particular protocol comes to the stage of IRB review is hardly addressed in the literature.

I am not claiming that the Belmont Report is somehow to blame for the absence of attention. I am suggesting, rather, that a byproduct of the relatively parochial focus on justice within research ethics, and exemplified within the Belmont Report, is the activities and decisions of these important social institutions or entities has been treated as falling largely outside of the purview of academics who focus on research ethics. Interestingly, this is not a perspective that has been shared.
by a variety of interest groups who have fruitfully engaged in both the political process and in social activism in order to ensure that the distinctive health concerns of their particular constituencies are represented within the broader research agenda. In this respect, the parochialism of key documents, such as the Belmont Report, may be partly responsible for the reactive, rather than proactive, tendencies of research ethics. It may also help to explain why those institutions that fund clinical research or that set policies that shape its aims and character are more likely to be pressured by interest groups than to have their decisions either informed or criticized by the research ethics community.

I also want to suggest that the parochialism of research ethics may be responsible for a tension that, if left unresolved, will pose a fundamental threat to the integrity of the discipline. The tension I have in mind arises from the combination of two factors. On the one hand there is the desire to ensure that clinical research does not function in a way that either recapitulates or exacerbates broader social inequities. On the other hand is the parochial focus of the current system in which such concerns are end-loaded into the process of IRB review. Together, these factors provide a recipe for a well-founded dissatisfaction on the part of researchers who may feel that they are unfairly singled out to rectify injustices or to fulfill duties that also either implicate or bind others who are not similarly scrutinized. Without careful consideration of the responsibilities of other stakeholders in the research enterprise, and how to coordinate multi-sectoral approaches to conditions that are intimately bound up with broader conditions of social or economic deprivation, the responsibility of mitigating the effects of such deprivation will continue to be assigned to clinical researchers. To the extent that researchers are only one group within a larger nexus of social entities and institutions that are responsible for the character and conduct of clinical research, they will rightly complain that the current system of ethical oversight is unfair. As long as the current system retains what I am calling its parochial focus, the tension between two goals that should be mutually satisfiable, namely, placing realistic demands on clinical researchers and ensuring that clinical research does not either recapitulate or exacerbate larger social inequities, will persist. Unless this parochial focus is left behind, then it may appear that the only feasible option for resolving this tension is to weaken our commitment to one of these competing moral demands.

An Agenda for the Future
The twenty-five years since the Belmont Report was first promulgated have witnessed a number of important advances in the ethical conduct of clinical research. The challenge facing research ethics over the next twenty-five years is to overcome the field’s still largely parochial attitude regarding considerations of justice. In order to do this, however, research ethics is going to have to find a way to overcome its agnosticism about broader questions of social justice without compromising its position as an action-guiding discipline that must secure the broad-based support of members of a pluralistic, liberal democratic community. These are significant challenges. In closing, I want to make a few remarks about how we might take a first step in this direction.

The first step requires a return to the insight expressed in the quotation from Rawls with which I opened this discussion. That is, research ethics needs to broaden its social perspective by recognizing that clinical research is one cooperative activity that takes place within a broader social division of labor. This social division of labor must be justifiable to the members of the community whose interests it is supposed to serve.2 Several facts about the role of clinical research within this larger social division of labor are particularly salient.

To begin with, scientific research is a cooperative enterprise that requires broad-based social support. It requires support from talented researchers who are willing to invest their time and energies in this endeavor, the commitment of important social institutions to provide space, resources, and logistical support, and the commitment of community members to participate in this enterprise and to support the social institutions that make it possible. Each of these different stakeholders may have a variety of reasons to undertake these commitments, including the prospect of economic benefit. However, one fundamental reason that all of these stakeholders share, and which makes possible many of the other reasons that may also contribute to their support of this endeavor, is the unique capacity of this enterprise to function as an engine of discovery. That is, by pushing back the boundaries of knowledge scientific research is able to generate the information and materials necessary to generate new understanding.

The social value of this information and understanding is fundamentally dependent on its integration into social structures that advance the health of community members. Although advances in understanding may be wondrous and worthwhile in their own right, I am suggesting that their social value lies primarily in their ability to enhance the capacity of basic social structures, such as the community’s health-care infrastructure, to meet the health needs of community members. From this perspective the legitimate claim of the research enterprise to the necessary support of community members hinges on its ability to enhance the capacity of other important social structures to meet the basic health needs of community members.

Finally, the way in which the basic structures of a community function has a profound influence on the health, welfare, rights, and opportunities of community members. But if, from the moral point of view, no community member has a justified claim to having his or her interests safeguarded and advanced to a greater degree than any other community member, then the community’s basic social structures should be shaped so as to provide equal support for the basic interests of all community members. This principle supports a regulative ideal according to which the health-care system should be capable of ministering with equal diligence and efficacy to the health needs of the diverse community members whose interests those structures serve. This regulative ideal might then provide a criterion that various stakeholders could use to evaluate the long-term direction of the clinical research enterprise and funding priorities.

Obviously, these ideas require significant philosophical development and refinement. However, such a broader perspective at least highlights as salient the need to answer a variety of questions that are under-represented in the current discussion of justice in research ethics. For example, are there social groups whose health needs are not understood with the same degree of accuracy, or met with the same degree of efficacy as those of their fellow community members? If so, how can the research enterprise contribute to the process of enhancing the capacity of the community’s health-related social structures to better meet those needs? Similarly, who are the stakeholders who should be charged with ensuring that the division of labor for achieving these goals is properly distributed across the various entities and institutions that are responsible for the research enterprise?

Clearly, there are many difficult questions that will have to be dealt with in the process of broadening the scope of justice in research ethics in this way. Unless the discipline is prepared to face these challenges head on, however, its capacity to
fulfill its moral mission will be hampered and perhaps even compromised in the long run.

Endnotes


Revisiting the Belmont Report: The Ethical Significance of the Distinction between Clinical Research and Medical Care

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The *Belmont Report* is a remarkable document. Published on April 18, 1979, this brief statement of Ethical Principles and Guidelines for the Protection of Human Subjects of Research has stood the test of time. The *Belmont Report* continues to be used as a valuable source of ethical guidance. In revisiting the *Belmont Report*, I want to focus on the vital ethical importance of distinguishing between the activities of clinical research and medical care. Two aspects of the *Belmont Report* are especially relevant for this focus: (1) the boundaries between practice and research and (2) the principle of beneficence.

Distinguishing Clinical Research and Medical Care

*Belmont* states, “It is important to distinguish between biomedical and behavioral research, on the one hand, and the practice of accepted therapy on the other, in order to know what activities ought to undergo review for the protection of human subjects of research.” This certainly is an important reason for recognizing and appealing to this distinction. Review and approval of research protocols by an independent committee prior to initiating research with human subjects constitutes one of the most important requirements for protecting research subjects from exploitation and harm. It is the procedural vehicle for overseeing the application of all the substantive requirements for ethical design and conduct of clinical research. In order for prospective review to serve as a regulatory mechanism for protecting research subjects, it is necessary to determine the purview of this oversight; hence the need to draw the boundary between medical care or practice, which does not require this type of regulation, and clinical research, which does. However, I want to examine here the distinction between medical care and clinical research from a different angle. I shall argue that this distinction is central to the purpose of the *Belmont Report*—to articulate “Ethical Principles and Guidelines for Research Involving Human Subjects”—rather than merely the basis for determining when ethics review is required.

*Belmont* helps to get started on this inquiry, but the journey will take us beyond the *Belmont* framework and will suggest ways in which that framework needs to be reconstructed. I start with the premise that clinical research is a socially valuable activity. As stated in the first sentence of *Belmont*, “Scientific research has produced substantial social benefits.” More specifically, clinical research has progressively transformed the practice of medicine, leading to substantial benefits to sick patients and to the public health. If we want to develop an ethical framework for a given legitimate activity, a set of principles and guidelines appropriate for governing that activity, then we need to begin with a correct understanding of the nature of the activity. This constitutes, I submit, a meta-principle for applied ethics in any given domain of legitimate human endeavor. Although this meta-principle may appear trivially true, it has been disregarded by much of the literature on research ethics. We need to understand what clinical research is, and what it is not, in order to identify and specify the ethical principles that apply to clinical research. A key to understanding the nature of clinical research for the purpose of developing appropriate ethical guidance is the distinction between clinical research and medical care.

This distinction is not hard to draw or to appreciate in the abstract. Yet in thinking about a major part of clinical research—clinical trials to evaluate the safety and effectiveness of treatments for patient-subjects—it is easy to conflate clinical research with medical care. However, this conflation has produced serious misconceptions about the ethics of clinical research.

*Belmont* helps pave the way in drawing this vital distinction between clinical research and medical care. *Belmont* characterizes the distinction as one between practice and research. More specifically, it is the distinction between the practice of medical care and clinical research. As *Belmont* states,

For the most part, the term “practice” refers to interventions that are designed solely to enhance the well being of an individual patient or client and that have a reasonable
expectation of success. The purpose of medical or behavioral practice is to provide diagnosis, preventive treatment or therapy to particular individuals. By contrast, the term “research” designates an activity designed to test an hypothesis, permit conclusions to be drawn, and thereby to develop or contribute to generalizable knowledge.

It is important to highlight what is central to this distinction. Medical care has a personalized focus. It is directed to helping a particular person in need of expert medical attention. Clinical research essentially lacks this purpose of personalized help for particular individuals. The definition of “research” in the Belmont Report needs to be read carefully. What makes clinical research distinctive is not merely testing a hypothesis or permitting conclusions to be drawn. The practice of medicine necessarily involves physicians formulating and testing diagnostic hypotheses to draw conclusions about what is wrong with a particular patient, which then leads to decisions about the appropriate treatment to recommend. The same point can be made about the term “experimentation,” which is often taken as a synonym for research. Medical care often involves experimentation in the process of finding treatments that work for a given patient and adjusting them so that therapeutic benefit can be maximized and side-effects minimized. Rather, as the Belmont definition makes clear, it is the aim of producing generalizable knowledge that distinguishes clinical research, including knowledge achieved by scientifically controlled experimentation with human subjects. Clinical research is primarily concerned with investigating defined groups of subjects, in contrast to the focus of medical care on individual patients. The purpose of inviting individuals to participate in clinical research primarily is not to help them but to develop generalizable knowledge about diseases and their treatment that can be used to help others in the future.

The distinctive purpose of clinical research, which makes it an essentially different activity from medical care, gives rise to the use of characteristic methods that are foreign to medical care. These include procedures such as random assignment of treatments, the use of placebo controls, and techniques to mask treatments so that patient-subjects, and often investigators, do not know which treatment they are receiving. They also include procedures to measure study outcomes that are not required for the medical care of research participants. In addition, scientific protocols governing clinical trials typically restrict flexibility in adjusting doses of study drugs and using concomitant medications. The ethical significance of these research methods is that research subjects are required to forgo the individualized attention characteristic of medical care, in which treatments are selected to be optimal for them and both patient and doctor know what treatment is being received. Instead, clinical trial participants are treated according to a protocol designed to generate scientifically valid data.

The distinctive purpose of clinical research to develop generalizable knowledge leads to two other key differences: the justification of risks and the nature of the relationship between physician-investigators and patient-subjects. In medical care, risks of diagnostic procedures and treatments are justified by potential medical benefits to the patients who receive them. There is an important exception, noted in the Belmont Report, in the case of organ transplantation involving living donors, in which the risks to one patient are justified by the benefits to another. But this does not change the pervasive orientation of medicine to seeking proportionality between risks and benefits for the particular patient seeking medical care. In clinical research, the risks of some interventions, such as experimental treatments, may be justified, at least in part, by the prospect of benefit to individual subjects. However, nearly all clinical research includes one or more procedures that carry burdens or risks to individual subjects without any compensating medical benefits to them. In some studies the entire set of procedures involving human subjects falls into this non-beneficial category. Randomized clinical trials, which evaluate treatments for patient-subjects diagnosed with a given condition, typically include interventions to measure study outcomes, such as blood draws, biopsies, lumbar punctures, or imaging procedures. These trials may include drug washouts before randomization to establish a drug-free baseline to assess treatment efficacy and avoid confounding the effects of study drugs with those of treatments taken prior to trial participation. Such procedures are necessary to generate scientifically valid data but do not provide any medical benefit to research subjects.

In view of these differences between clinical research and medical care in purpose, methods, and justification of risks, the relationship between investigators and research subjects is ethically distinct from the relationship between doctor and patient. We have well-developed conceptions of the doctor-patient relationship from an ethical perspective encompassing the ancient Hippocratic approach of medical paternalism and various models of shared decision-making that incorporate respect for patient autonomy. The investigator-subject relationship has not received the systematic ethical attention it deserves. We tend to see this relationship by way either of its continuity or contrast with the doctor-patient relationship, rather than being defined by an ethical framework appropriate to clinical research.

### Confusing Research and Care: The Therapeutic Orientation to Clinical Research

Despite the clear differences between clinical research and medical care in purpose, methods, justification of risks, and the nature of the relationship between investigators and subjects, it remains easy to conflate and confuse the two activities in the concrete circumstances in which clinical research takes place. I call this conflation “the therapeutic orientation” to clinical research. Clinical research is conducted by physicians in hospitals and, increasingly, in doctors’ offices. Investigators and members of the research team wear white coats. Instruments and procedures commonly used in medical care are also employed for research purposes. In addition, the language used to describe clinical research contributes to confusion. Subjects are often referred to as “patients” and investigators as “doctors,” without any qualifiers indicating that an activity distinct from medical care is being pursued. Clinical trials are often described as “therapeutic research,” and investigators as having a “therapeutic intent.” The website for M.D. Anderson, a leading cancer research and care center, asserts that “A clinical trial is just one of many treatment options at M.D. Anderson,” suggesting that the scientific experimentation of clinical trials is a form of medical therapy. Advertisements aimed at recruiting research subjects typically appeal to patients suffering from disease and seeking therapy.

These factors lead to a tendency observed in patient-subjects to conflate and confuse research participation and medical care, producing a phenomenon known as “the therapeutic misconception.” Patients enrolled in clinical trials often see their participation as subject to the same personalized patient-centered orientation that is characteristic of medical care. Investigators also may harbor therapeutic misconceptions about clinical research.

Moreover, ethical thinking about clinical research also displays a misguided therapeutic orientation. The basic idea that physicians are devoted to the health and well being of their patients is so deeply ingrained that it is difficult to grasp that in
clinical research conducted by physicians in clinical settings the primary obligation is different. The primary obligation of researchers is to pursue scientific investigation according to a study protocol, not to promote the health and well being of patients enrolled in research. The conflation between the ethics of clinical research and the ethics of clinical medicine is notably manifested in The Declaration of Helsinki, which stipulates “ethical principles for medical research involving human subjects.” Principle number 3 states, “The Declaration of Geneva of the World Medical Association binds the physician with the words, ‘The health of my patient will be my first consideration.’” This is certainly a sound principle for the ethics of therapeutic medicine; however, its appearance in the leading international code of ethics for clinical research is puzzling. It implies that clinical research should be governed by the patient-centered therapeutic beneficence characteristic of medical care.

Clinical Equipoise

The prevailing ethical thinking about clinical trials invokes the principle of “clinical equipoise,” and thereby attempts to assess and to justify these scientific experiments in terms of the therapeutic physician-patient relationship. According to this principle, a clinical trial is ethical only if the expert medical community is uncertain about the relative therapeutic merits of the experimental and control treatments evaluated in the trial. When a state of clinical equipoise exists, no patient will be randomized to a treatment known to be inferior to available therapeutic options, thus making clinical trials compatible with the therapeutic obligation of physicians to treat patients according to a scientifically validated standard of care. Benjamin Freedman and his colleagues assert that “As a normative matter, it [clinical equipoise] defines ethical trial design as prohibiting any compromise of a patient’s right to medical treatment by enrolling in a study.” According to the principle of clinical equipoise it is wrong to randomize a trial participant to a placebo control when proven effective treatment is available for the participant’s medical condition. Clinical equipoise “foreclose[s] the use of placebos in the face of established treatment, because enrolling in a trial would imply that a proportion of enrollee will receive medical attention currently considered inferior by the expert community.”

Clinical equipoise was proposed as a solution to an ethical problem known as “the RCT dilemma”: How is it possible to conduct randomized trials enrolling patients in need of medical treatment without violating the therapeutic obligation of physicians to promote the medical best interests of patients. Fred Gifford described this dilemma as follows:

The central dilemma concerning randomized clinical trials (RCTs) arises out of some simple facts about causal methodology (RCTs are the best way to generate the reliable causal knowledge necessary for optimally-informed action) and a prima facie plausible principle concerning how physicians should treat their patients (always do what it is most reasonable to believe will be best for the patient).

I contend that in view of the distinction between clinical research and medical care, the RCT dilemma is spurious. One horn of the dilemma is fundamentally misplaced. That physicians should have undivided loyalty to doing what they believe is best medically for their patients is certainly a plausible principle for medical care. However, it is not a plausible principle for governing the relationship between investigators and research subjects. Since the clinical trial should be conceived as a controlled experiment to evaluate treatments scientifically rather than as a form of personalized medical therapy, it is difficult to see why the therapeutic obligation of physicians or the right of patients to optimal or standard medical care must govern thinking about the ethics of randomized trials. Specifically, it is difficult to see why in the context of research it is always wrong per se to provide less than standard treatment in the form of a placebo control. Use of a placebo may be wrong because it is not methodologically necessary for a valid test of the study hypothesis, or because withholding treatment is likely to cause serious harm. Yet to see it as wrong because it compromises the patient’s right to medical treatment conflates research with therapy.

Specifying Principles for the Research Context

The differences between clinical research and medical care that I have outlined call for articulating a set of ethical principles governing clinical research that are not the same as those governing medical care. The Belmont Report does not provide a fully satisfactory guide for this project. Belmont identifies three principles to guide research involving human subjects: respect for persons, beneficence, and justice. All three properly apply to both medical care and clinical research. However, the Belmont Report does not adequately clarify or emphasize how the meaning of these principles differs importantly in clinical research as compared with medical care. Consider the principle of beneficence. In the case of medical practice, beneficence is specified in terms of the personalized therapeutic purpose of medical care. Physicians providing medical care aim at promoting the health of particular patients and avoiding interventions that pose risks to patients that are not justified by their potential for therapeutic benefit. In contrast, clinical research aims to benefit future patients and society and exposes subjects to risks for the sake of generating scientific knowledge. Accordingly, beneficence in clinical research must be understood as permitting, within appropriate limits, social benefits from producing health-related knowledge to justify risks to subjects. Nothing in Belmont is inconsistent with understanding beneficence and nonmaleficence as being different in clinical research, as compared with medical care, but the key difference in the justification of risks is not highlighted and given the emphasis it deserves.

Ethical Problems with the Therapeutic Orientation

What is wrong from an ethical perspective with the therapeutic orientation to clinical research? First, it produces false moral comfort about clinical research. Using some for the good of others is inherent in clinical research. The therapeutic orientation makes it appear that in pursuing research investigators are, or should be, maintaining intact their therapeutic obligations to patient-subjects. This distorts the moral climate and diverts attention from the potential for exploitation in the research enterprise. Second, the therapeutic orientation may contribute to subtle exploitation insofar as it encourages investigators to use their authority as physicians to secure participation in research—an activity that is not aimed at the best interests of subjects. This is of greatest concern when there is a prior therapeutic relationship between the physician-investigator and the prospective research subject. Third, the therapeutic orientation to research interferes with the development of a proper sense of professional integrity among investigators. Integrity involves coherence between beliefs and conduct. Unlike medical care, clinical trials typically include procedures designed to generate valid scientific data, which are known to pose risks to subjects that are not compensated by potential benefits to them, for example, a biopsy performed solely to measure study outcomes. When physician-investigators see patient volunteers and themselves in the guise of the therapeutic physician-patient relationship, while they conduct research activities that depart significantly from the ethical framework.
of medical care, their professional self-understanding lacks integrity.

Fourth, the therapeutic orientation interferes with the full realization of informed consent to participate in research. Patients haven’t consented to research if they think of it simply as therapy. It is likely that a therapeutic orientation to research by investigators fosters the therapeutic misconception among patient volunteers. If investigators view the ethics of clinical research through a therapeutic lens, how can we expect research subjects to be clear about how their participation in research differs from the context of medical care?

Finally, the therapeutic orientation fails to provide adequate guidance regarding what types of clinical trials are ethically acceptable. Appealing to the principle of clinical equipoise, this ethical perspective rules out scientifically valuable placebo-controlled trials that do not pose undue risks of harm. The ethical justification of placebo-controlled trials involves complex issues of methodology and risk-benefit assessment that I can’t address here. However, it is worth repeating that when we bear in mind the distinction between clinical research and medical care, the fact that the use of a placebo control withholds proven effective treatment is not, in itself, a sufficient reason to reject its use. Placebo controls are no different in principle from any other research procedures that pose risks to subjects without compensating benefits to them.

### Objections

I now consider three objections to drawing such a sharp distinction between clinical research and medical care. First, it violates the meta-principle invoked at the outset, which directs us to develop ethical principles that comport with the nature of the activity in question. Clinical research is conducted in close proximity with medical care. Indeed, the randomized clinical trial, according to this objection, ought to be seen as combining research with medical care. The point of a principle such as clinical equipoise is to specify the conditions under which it is ethical to combine these two activities, such that research participation does not compromise medical care.

It is true that randomized trials enroll individuals diagnosed with medical conditions and that treatments for these conditions are provided and evaluated in these trials. But to describe randomized trials as combining research and medical care flies in the face of the fundamental differences between these activities in purpose, characteristic methods, and justification of risks. To receive treatment in a randomized trial, governed by a research protocol designed to achieve scientifically valid results, is to forgo the personalized attention of medical care. A sharp ethical distinction between clinical research and medical care is needed precisely because within the context of clinical research physician-investigators cannot legitimately promise undivided loyalty to doing only what is best medically for patients.

A related objection is that physician-investigators don’t cease being physicians just because they are conducting research. Instead of dismissing the therapeutic obligation or the duty of care as irrelevant to clinical research, these ethical norms binding physicians ought to be understood as governing clinical research, albeit with some modifications that reflect methodological requirements necessary to conduct valid research. I have argued that strict compliance with the principle of therapeutic beneficence would make clinical research impossible to conduct, as it would prohibit any research interventions that pose risks to subjects without compensating medical benefits. On the assumption that clinical research is an ethically valuable activity, it follows that physician-investigators should not be held to the same therapeutic obligations or duties of care as in the practice of medicine. To be sure, it remains possible to affirm a qualified therapeutic obligation in research that departs from a requirement to offer patients optimal or standard medical care. However, this position risks encouraging the therapeutic orientation to clinical research, thus giving rise to all the problems with the therapeutic orientation that I have pointed out. Nor is anything important ethically lost by rejecting the therapeutic obligation of clinical researchers, as I shall argue in response to a third objection.

The third objection is that the effort to distinguish the ethics of clinical research from the ethics of medical care is bound to leave research subjects without adequate protection. It opens the door to rampant exploitation under a utilitarian ethic, which sanctions sacrificing the well being of research subjects for the sake of scientific progress and societal benefit. However, from the claim that research ethics is not properly governed by therapeutic norms, it does not follow that “anything goes,” that there are no ethical constraints on scientific investigation to protect research participants. In other words, to argue that investigators do not have the same therapeutic obligations to patients in the context of clinical research as in medical care does not imply that they have no obligation to protect research participants from harm and exploitation. My bioethics colleagues at the NIH, Emanuel, Wendler, and Grady, explicate seven ethical requirements of clinical research, drawing in part on the Belmont Report. These requirements include: (1) that research projects aim at socially valuable health-related knowledge; (2) that rigorous methods are used to produce scientifically valid data; (3) that subjects are selected fairly; (4) that research protocols have a favorable risk-benefit ratio, which involves minimizing risks and justifying them by the prospect of medical benefits to research subjects and/or the value of knowledge to be gained; (5) that research protocols receive independent committee review and oversight; (6) that informed consent is obtained; and (7) that enrolled research participants are treated with respect during the course of research. These requirements can, and should, be understood in a way that does not imply that research is governed by the ethics of therapeutic medicine. Together they provide the grounds for robust protection of human subjects while permitting valuable research to proceed.

### Conclusion

In revisiting the Belmont Report, one sentence stands out for me as central in highlighting the challenge of research ethics: “Beneficence thus requires that we protect against risk of harm to subjects and also that we be concerned about the loss of substantial benefits that might be gained from research.” In research ethics we can err in two ways: on the one hand, we can fail to provide adequate protection of research subjects, and, on the other hand, we can prohibit valuable research that does not pose undue risks of harm. How, then, can we balance the protection of subjects with achieving the social value that flows from clinical research? The therapeutic orientation, which conflates the ethics of clinical research with the ethics of medical care, gets in the way of facing this challenge. Central to the task of the Belmont Report, to articulate ethical principles and guidelines for research involving human subjects, is to recognize and appreciate the ethical significance of the distinction between clinical research and medical care.

### Endnotes

3. www.mdanderson.org
Sinai’s Visiting Doctors Program, which provides primary care for home-bound people. Our patients are generally elderly and infirm, and a good number of them are in the late stages of long-standing illnesses. Many are terminally ill and express the desire to die at home.

Our program works closely with home nursing agencies, home hospice services, and a wide array of community-based agencies to create a network of support that allows our patients to remain with their families in familiar surroundings to the very end.

To my mind, this is what patient-centered care is all about. In their own homes, our patients and their families feel comfortable taking matters of life and death into their own hands. If it suits their needs, and it usually does, we will do whatever is necessary to keep them away from the emergency room and out of the hospital.

For a doctor, a home visit lies outside the hectic pace of traditional hospital and clinic settings; it provides a chance to go beyond the thumbnail sketch and curb-side consult that rarely do patients justice. Communication—and the high-quality care that results—takes time because questions have to be answered, details spelled out, reassurances given, and the whole lot repeated until everyone agrees and understands. More than two-thirds of our patients are able to die at home. This is in sharp contrast to the national figure of two-thirds of patients dying in hospitals or skilled nursing facilities (often despite their wishes to die at home). We think that our statistic is even more impressive considering how much effort and coordination it takes to get everyone on the same page. Everyone has to come to terms with death intellectually, emotionally, and spiritually. And everyone has to know what to do when the patient dies: Call the doctor, call hospice, or call the funeral home, but don’t call 911.

Mrs. Santos’s Story

When I first met Mrs. Santos in her home—in fact, every time I ever saw her—she was sweating and had a rapid heart rate. I soon came to understand that despite the smile this small, lively woman always wore, she was in excruciating pain. During an earlier hospital stay, our medical center’s palliative care staff was amazed at the doses of morphine-based pain killers needed to keep her symptoms at bay. Once Mrs. Santos’s pain seemed controlled and the care plan was clarified with her and her family, she was sent home to be cared for by hospice nurses and those of us in the Visiting Doctors Program.

Mrs. Santos was living just blocks from our hospital, in the projects of Spanish Harlem. Everything about these buildings is intimidating: their hulking size, the desolate look of the lobby, the smell in the elevator. Even the long, narrow hallways, although they aren’t longer or narrower than other hallways, can seem menacing to the uninitiated.

The two-bedroom apartment was clean but cluttered, with a seemingly endless stream of people, faces, voices. It was active, even animated—very much alive. On one occasion, late in Mrs. Santos’s care, I entered the living room and found ten family members sitting around an enormous wire cage filled with crabs and chunks of coconut. They’d let the crabs feed on coconut for a few weeks, I was told, and then have a real Dominican crab feast. They were all sitting around watching the crabs grow.

On my first visit, Mrs. Santos was waiting for me in her bedroom. It was filled almost to capacity with her hospital bed, oxygen compressor, hydraulic lift for getting her out of bed, bedside commode, and medicine chest. I alternated between sitting on the radiator and standing. She was fifty-two years old and dying of widespread cancer. Her cancer almost filled her abdominal cavity; it had spread extensively throughout her...
lungs, and a large mass near her spine was crushing her spinal cord, leaving her paralyzed from the waist down. She had an enormous bedsore. She also had severe shortness of breath and required supplemental oxygen.

Immobiled in bed, Mrs. Santos was always impeccably clean and always smelled good. She also was the most stoic person I’d ever met. Whether it was her deeply held religious beliefs or her devotion to and passionate love for her family, something kept this remarkable woman suspended above her travails. She smiled through it all, even when she was smiling through clenched teeth.

After her most recent hospital stay for pain management, during which the children had battled openly among themselves about where their mother should go after leaving the hospital, one of her daughters had taken charge and taken her in. Mrs. Santos had raised five children as a single parent and loved them all equally, which made the thought of living with only one of them awkward for her. Her other children remedied this by visiting often and filling the apartment with her grandchildren at all hours of the day and night. For her part, she was happy to be in a family home, happy to be surrounded by family.

She was also in great pain. The usual starting dose of oral morphine is 5 mg every two to four hours. When I met Mrs. Santos, her intravenous pain regimen was the equivalent of about 500 mg of oral morphine every hour.

Although her family understood that she had very little time to live, Mrs. Santos insisted that she would be fine and refused to discuss matters further. She was willing to appoint the daughter in whose apartment she lived as her health-care proxy, but, other than agreeing to a DNR order, she wouldn’t specify her wishes for end-of-life care, refusing to discuss such things as whether she would accept artificial nutrition and hydration. We completed, and I signed, an out-of-hospital DNR form, and I made sure that the Visiting Doctors’ phone number was prominently displayed. Mrs. Santos spoke no English, and I hadn’t had the good sense to learn Spanish, so her daughter served as translator. Our direct communication was limited to sparkling smiles (hers) and knowing glances (also hers). She was fortunate to have a caring and devoted daughter who was determined to give her the same loving care that her mother had shown in raising her children.

Preparing for death has its own ritual. It requires many family meetings, innumerable phone calls, lots of reassurance, and a great deal of reinforcement. It is critical that the family and patient have easy and immediate access to a nurse and doctor, as well as proper documentation at home on the patient’s wishes about resuscitation, including—and this is essential—an out-of-hospital DNR form.

New York is one of the more than twenty states that has an out-of-hospital DNR law intended to ensure that emergency medical services (EMS) personnel do not resuscitate terminally ill people at home against their wishes. If EMS personnel are called to the scene, they are required by law to perform life-saving measures unless there is an out-of-hospital DNR form or an EMS-affiliated doctor orders them not to resuscitate. Although many patients have thought through their advance directives and have living wills and health-care proxies, none of these are valid in the home setting. Presumably this is because it’s unreasonable to expect EMS personnel to read and interpret the validity of these documents during an emergency.

I visited Mrs. Santos at home once a week. At every visit she went to great lengths to convince me that she was feeling okay, her appetite was excellent, she was eager to be out of bed, her pain wasn’t that bad. The truth was that before entering Mrs. Santos’s room, I would get a reality check from her daughter. It was during these hallway discussions that I found out how much time her mother spent crying and trembling from pain every day, and how she begged her mother to accept a rescue dose of pain medication that was invariably refused. Despite Mrs. Santos’s stoicism, we had to increase her pain medication, and by the second week she was intravenously getting an hourly equivalent of almost 1,200 mg of oral morphine. Her five children were always present in some combination, and the apartment was teeming with grandchildren sneaking in to steal a curious peek at Grandma and getting a knowing wink for their efforts before an adult shooed them out.

As the weeks passed, Mrs. Santos and I developed our own rapport. I tried hard to respect her wish that the pain medication not be increased, despite her escalating pain, if it was going to make her sleep all the time. And, in response to a food craving she repeatedly mentioned, I surprised her one day with a double cheeseburger and fries from McDonald’s. I was as good as family after that.

Other than her inexorable decline, the visits were always the same. Mrs. Santos never stopped talking to me about her family, and she never agreed to aggressive pain control that would make her lethargic. By the fifth week, and my fifth visit, she began to accept that she was dying. She was profoundly emaciated, sweating profusely, and burning with fever. Crying and barely able to speak clearly, she asked that we call her priest and agreed to have stronger pain medication once she had made her peace with God.

When I visited four days later, she had seen the priest, and her entire family had gathered to say goodbye. She had not spoken in forty-eight hours and was unresponsive. We increased her pain medicine one last time, and the family and I once again reviewed what needed to be done when she passed away.

The Plan Goes Wrong

The following afternoon I got a call from my office that Mrs. Santos’s family needed to get hold of me right away. I called, and when someone on the other end picked up, all I heard was screaming, crying, chaos. Mrs. Santos’s daughter yelled over the din. “They’re doing things to her! You have to make them stop! They won’t let me in the room!” I managed to blurt out a few words. “Who? What are you talking about?” The daughter told me. “EMS came and they’re doing things to her. I think the neighbors called them, and they won’t stop doing things to her!” Still confused, I asked, “What are they doing?” Her frantic reply: “She died half an hour ago! Then they came into my apartment, and they won’t stop working on her! They say I don’t have the paper and they won’t leave her alone!”

It was then that I realized what had happened. Mrs. Santos had died a peaceful death, the death she and her family had hoped for. Her bereaved family, especially her young grandchildren, had begun sobbing so loudly that a neighbor heard and called 911. When EMS arrived, they demanded to see her out-of-hospital DNR form. Then, when the family couldn’t produce it, the emergency medical technicians (EMTs) put her on the floor and proceeded to perform advanced cardiac life support on Mrs. Santos’ dead body. They wouldn’t stop, wouldn’t speak to my nurse when the panicked daughter first called for help, wouldn’t speak to me on the phone, and had locked the family out of the bedroom.

Fortunately, Mrs. Santos’s family lived only a few blocks from our office. I grabbed a blank out-of-hospital DNR form as a precautionary backup, filled it out, and signed it. Then I hopped in a cab and rushed toward the apartment. The trip took less than ten minutes, but it was enough time to allow me to go from being blind with rage to rational decision-making mode. I’d started the ride hoping for a confrontation with EMS that would involve the police, but by the time I was in the building’s
But Don’t Call 911

Historically, the option to refuse cardiopulmonary resuscitation (CPR) exists because of resuscitation’s dismal success rate: only 1-2 percent for out-of-hospital sudden cardiac death. And that’s for a typically healthy businessman who collapses on the subway platform from a heart attack, not for someone dying of a terminal illness.

EMS protocol is obviously designed to protect patients and families—as well as EMS personnel. No one wants to make a judgment call in the heat of the moment and with inadequate supporting information that withholds needed treatment. Yet this well-intentioned policy can fly in the face of everything that families, nurses, and doctors do to help people die quiet deaths at home. That’s what went wrong for Mrs. Santos. It is not in New York, so it wouldn’t have helped Mrs. Santos. It is accepted as an advance directive in many states—although not in New York, so it wouldn’t have helped Mrs. Santos. It is an advance directive in many states—although not in New York, so it wouldn’t have helped Mrs. Santos. It is a seemingly foolproof method of communicating a patient’s wishes in a disturbingly unpredictable world.

A piece of paper that provides an out-of-hospital DNR order is easily misplaced, as Mrs. Santos’s family tragically discovered. That’s probably why wearing a low-tech DNR MedicAlert bracelet is slowly gaining acceptance. Typically, these bracelets convey clinical information to EMS personnel in situations where the patient can no longer communicate. The bracelets are accepted as an advance directive in many states—although not in New York, so it wouldn’t have helped Mrs. Santos. It is a seemingly foolproof method of communicating a patient’s end-of-life wishes.

Reaching an understanding on quality-of-death issues with dying patients such as Mrs. Santos is part of good doctoring. In health care, and especially in home care, the combination of clear communication and time work to create a harmony that is the backdrop to a well-orchestrated death. It’s also the only way to try to safeguard patients’ wishes in a disturbingly unpredictable world.

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This is for My Grandmother

Felicia Nimue Ackerman
Brown University

This is for my grandmother, Carolyn Colby.
“Terminal cancer,” the doctor said. His eyes filled with tears.
“I’ll get you the best hospice care in Boston,” he put his arm around her.

My grandmother’s eyes were cloudy but dry. She said, “I’m 84, I’ve had a good life, so I don’t want to die. I want experimental treatment.”

“That would ruin the time you’ve got left,” the doctor said. My grandmother said, “I’ll risk it,” and she did.

And died of a stroke.

On her 93rd birthday.

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Principlism

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Principlism is characterized by its citing of principles which constitute the core of its account of biomedical ethics; for Beauchamp and Childress these principles are: beneficence, autonomy, non-maleficence, and justice. The account of Beauchamp and Childress is so entrenched in the minds of some bioethicists that clinical moral problems are often grouped (for conferences, papers, and books) according to which principle is deemed most relevant and necessary for resolving them. It has become fashionable and customary to cite one or another of these principles as the key for resolving a particular biomedical ethical problem. Throughout much of the medical bioethical literature authors seem to believe that they have provided a theoretical solution to the problem being discussed when they have mentioned one or more of the principles. Thus, not only do the principles presumably lead to acceptable solutions, but they are also treated by many as the ultimate grounds of appeal.

We examine principlism by looking at its undeniably leading account, that of Beauchamp and Childress, as manifested in the many editions of their book, Principles of Biomedical Ethics. Their account is the very best the position has to offer, and it is their account that has pervaded the world of biomedical ethics. For many years it has provided the conceptual framework of the Georgetown Intensive Bioethics Course, a one-week summer course that has been attended by thousands from the United States as well as from around the world. Beauchamp and...
Comparison of Common Morality and Principlism

As we have emphasized in several previous articles on principlism, we are criticizing Beauchamp and Childress as the very best spokesmen for the principle-based approach to bioethics. However, we are concerned about the wide spread popularization of principlism throughout the biomedical ethics world, where the use of principles simply masks ad hoc and unreasoned decisions and judgments. Beauchamp and Childress are very careful not to use their principles to resolve any controversial issue; they simply use the principles to focus their discussion of particular issues. It is crucial to distinguish between using principles as a guide to decision-making and as a way to focus discussion of issues. Their discussions of these issues are always quite knowledgeable and often quite insightful. Our objection is to the framework they claim to be using. Even though Beauchamp and Childress have changed their theoretical account considerably over the years, their discussion of particular cases has not changed. Our concern is with the practitioners of principlism who do not realize that its point is to focus discussion and not to resolve any controversial issues. We think it is important to emphasize this point because principlism is still flourishing.

Their Fourth Edition (1994) so modified their account in response to criticisms that one reviewer entitled his article “The Beginning of the End of Principlism,” and said that their new claims “constitute a radical change and herald the end of ‘principlism.’” The Fifth edition (2001) devotes even more space to theoretical issues, including a misguided criticism of our account. It is misguided because although we provide an account of common morality that explains the moral decisions and judgments of ordinary thoughtful people, Beauchamp and Childress continue to regard our theory as an “impartial rule theory.” Further, they label as common morality theories, the purely schematic accounts of W. D. Ross and William Frankena, which like principlism itself, consist of nothing but a set of principles or prima facie rules, with no system in which they are embedded. Like Ross and Frankena, Beauchamp and Childress have no account of the nature or role of impartiality, and no distinction between the moral rules, to which obedience is required, and moral ideals, which people are encouraged to follow. Their only account of the procedure to be used when there is a conflict between the principles is that the principles should be specified, but they do not provide even one example of how this specification works to resolve a controversial problem.

Beauchamp and Childress have conflicting views about morality. They say, “In its most familiar sense, morality refers to norms about right and wrong human conduct that are so widely shared that they form a stable (although usually incomplete) social consensus” (pp. 2-3). This innocuous sounding statement leads them into errors; by concentrating on right and wrong human conduct, that conduct to which the moral rules apply, and neglecting good and bad human conduct, to which the moral ideals apply, they make it seem as if morality consists of nothing but prohibitions and requirements. They then say, “All persons who are serious about living a moral life already grasp the core dimensions of morality. They know not to lie, not to steal property, to keep promises, to respect the rights of others, not to kill or cause harm to innocent persons, and the like” (p. 3). Their listing of the rules of morality is remarkably similar to our list of the rules of common morality; however, they then go on to say the following. “We will refer to the set of norms that all morally serious persons share as the common morality. The common morality contains moral norms that bind all persons in all places” (p. 3).

They then distinguish between common morality and morality by claiming that common morality consists of “norms that all morally serious people accept as authoritative” whereas morality includes those norms that “bind only members of specific moral communities.” They misleadingly used the phrase “moral ideals” to refer to those norms that “bind only members of specific moral communities,” that is, to prohibitions and requirements that are not universal. The full quote goes as follows: “Morality consists of more than common morality, and we should never confuse or conflate the two. For example, morality includes moral ideals that individuals and groups voluntarily accept, communal norms that bind only members of specific moral communities, extraordinary virtues, and the like. The common morality, by contrast, comprises all and only those norms that all morally serious persons accept as authoritative” (p. 3). Thus, according to Beauchamp and Childress, neither common morality nor morality includes what we have termed “moral ideals,” those precepts that are universally regarded as morally good to act on, but which are neither prohibitions nor requirements. This restriction of common morality to the moral rules, and of morality to duties and aspirations of particular groups, excludes what we call the universal moral ideals, such as helping the needy. Their failure to acknowledge that there are universal moral ideals may explain why they do not recognize that our theory, unlike theirs or those of Ross and Frankena, does in fact explain the moral decisions and judgments of all morally serious persons. Our account of common morality makes clear that all morally serious persons recognize that common morality consists of more than universally accepted rules; it also includes universally accepted moral ideals. Even many moral codes of particular groups and societies consist of more than binding duties and extraordinary virtues; they also include aspirations that all members of the group are encouraged, but not required to follow.

It is universally recognized that, when not breaking any moral rule, taking a serious risk in order to save the lives of innocent children is morally commendable, but not morally required. Nonetheless, when breaking a promise would not involve serious harm, taking a serious risk to save innocent children justifies breaking that promise, even though keeping promises is a “norm that binds.” Common morality not only includes universally accepted moral ideals, but also includes a procedure for determining whether a violation of a moral rule is strongly justified, weakly justified, or unjustified. Not only do they falsely limit common morality to “norms that bind,” but also they ignore all those formal features of common morality that we put forward in our discussion of morality. Furthermore, they do not explicitly acknowledge that common morality allows for some unresolvable moral conflicts.

It is clear that although Beauchamp and Childress use the phrase “moral ideals,” they do not mean by it what we mean. They explicitly deny that moral ideals in our sense are part of common morality. They say, “There are two levels of moral standards: ordinary moral standards and extraordinary moral standards. The first level is limited to standards in common morality that pertain to everyone. These standards form the moral minimum” (p. 39). Thus, according to Beauchamp and Childress, common morality is the moral minimum. But, contrary to Beauchamp and Childress’s account, all morally serious persons agree that common morality includes more than the moral minimum. All agree that it is morally good to act on the moral ideals whenever one can do so without violating a moral rule. Everyone also agrees that even when acting on an
ideal requires breaking a moral rule, it is sometimes justified to break the moral rule. Beauchamp and Childress apparently do not realize that common morality consists of more than moral rules. They fail to include in common morality the moral ideals and the two-step procedure for determining how to act when moral rules conflict or a moral rule conflicts with a moral ideal. Among the consequences of these failures is the holding the mistaken view that common morality being a system requires that there be a unique best solution to every moral problem.

Beauchamp and Childress say, "A virtue of our theory is that it requires specification...and a problem in Clouser and Gert's account is that it supposes that its "more concrete" rules escape the need for specification. Only a theory that could put enough content into its norms to escape conflicts and dilemmas in all contexts could live up to the Clouser-Gert demand, but no theory approximates this ideal." This quote demonstrates the fundamental flaw of all forms of principlism, namely, that the various principles are not embedded in a system, so everything has to be packed into the principles. But as Beauchamp and Childress admit there is no way to "put enough content into" any principles in order for them to deal adequately with the complex moral problems that any account of morality must face. We do not claim that our rules escape the need for specification because they are more concrete, but because the rules of common morality are embedded in a comprehensive moral system with a two-step procedure that includes the morally relevant features needed to describe any proposed violation of a rule, and a formula that uses this description when deciding on which way to act. Further, not only do we not claim to "escape conflicts and dilemmas in all contexts," we explicitly claim that some disagreements are unresolvable. But, unlike Beauchamp and Childress, we try to explain why this is so.

Beauchamp and Childress seem to have adopted the concept of "specification" from Henry Richardson. We have already replied to Richardson, but it may be worthwhile to make clear again the advantages of recognizing that the moral rules are embedded in a system, rather than regarding each of the principles as a freestanding principle. When, in our reply, we praised Beauchamp and Childress's "adoption of specification...as a way station on the journey to truth—that is to [our] own alternative view of the moral rules governing bioethics," we did not realize that their adoption of Richardson's proposal to improve principlism by means of specification was a last ditch effort to maintain the view that morality operates with a set of free-standing principles. It is interesting and instructive that Beauchamp and Childress never discuss the possibility that in some circumstances there is no uniquely correct way to specify the principles. They seem to hope that specification will enable them to provide uniquely correct solutions to every moral problem. Thus they seem to be abandoning the one truly valuable aspect of principlism, viz., that it did not provide uniquely correct solutions to every moral problem. But they are still ambivalent about this, maintaining their original view while at the same time putting forward specification as if it will resolve all disagreements.

The contrast between our theory and that of principlism is stark. Beauchamp and Childress start with freestanding moral or bioethical principles and then modify or specify these principles in order to apply them to particular cases. On the other hand, we start with common morality, a moral system that we neither change nor modify. This system enables us to provide morally relevant descriptions of all the particular cases in a way that makes clear how the moral rules apply to them. Rather than continually reformulating the rules for each particular case, we keep the rules unchanged and instead provide a procedure for determining whether it is morally justified to violate the rule in these circumstances. We even distinguish between strong and weak justification, that is, between the clear cases and the controversial ones. Keeping the moral system unchanged keeps the focus on the facts (where it should be) and avoids the continuing reformulation of the moral rules or principles in order to apply them to each particular case.

And Beauchamp and Childress do adjust, interpret, and specify principles in order to apply them to particular cases. This means that the principles become more complex and are constantly changing, and thus are not known with any precision to almost any one. We, on the other hand, keep the moral system constant, (morality does not change), and thus it is known to all. However, we provide ways of describing a particular case via the morally relevant features, so that it becomes clear how the moral system applies to that case. For us, the work is done in preparing the particular case, e.g., finding out all the facts, categorizing how the morally relevant features fit, etc., so that the moral system can be applied to it. If the goal is to connect common morality to a particular case, there are two opposing ways to do this. One way is to work on describing the case so that it becomes clear how the moral system applies to it, which is what we do. The other way is to continually specify their principles so that they can be applied to the particular case. Since Beauchamp and Childress have no system, they cannot work on describing the case in the appropriate way and so must adopt the second method.

In deciding between two accounts of morality, one that involves a continual revision of moral principles, such that these principles are unlikely to be known by most of the people to whom they apply, and an account of morality that is known to everyone to whom it applies, the choice seems clear. Further, if the second moral theory focuses on the facts in a way that requires people to describe the moral situation in a way that rules out their personal or cultural biases, whereas the first provides no limits on the way in which the moral principles can be specified, again the choice is clear. Finally, if the second moral theory requires one to view every violation of a moral rule in the way that an impartial rational person would, whereas the first allows one to avoid violations simply by specifying the bioethical principles without involving impartiality at all, again it is obvious which should be chosen.

Specification brings out the ambivalence that Beauchamp and Childress seem to have with regard to the view that a moral theory must provide a unique correct answer to every moral question. On the one hand, they want to hold onto the attractive feature of early principlism, namely, that it did not even pretend to provide a method for arriving at a unique correct answer; on the other, they now want a method for doing just that. They admit that "In any given problematic or dilemmatic case, several competing specifications may constitute possible resolutions, which returns us to conflicts of the sort that drove us to specification in the first place" (p. 17). Instead of recognizing that not all problematic or dilemmatic cases can be resolved, they say, "We therefore must connect specification as a method with a larger model of justification that will support some specifications over others" (p. 18).

We recognize that not all moral problems have unique best resolutions and do not propose any method whereby they can all be resolved. Beauchamp and Childress seem to accept the standard view of moral theories that common morality always provides a unique correct answer to every moral question about how one morally ought to act. Thus they are inclined to hold that all moral disagreements must be explained away. Those who disagree must be not equally informed, not impartial, or not rational. If two people who hold this standard view are discussing a controversial moral issue and disagree with each
other, each must regard the other as not fully informed, not impartial, or not rational. These are not the attitudes that make for a respectful and fruitful discussion of a controversial moral issue. However, if both hold the view that morality does not provide unique correct answers to all moral questions, then they may conclude, usually correctly, that this is one of these issues. Thus, they need not regard the other person’s view as morally unacceptable, and can cooperate in trying to discover a compromise that comes closest to satisfying both of their positions.

It is usually clear if the disagreement is based on a difference about the scope of morality. Most disagreements about abortion and the treatment of animals have their source in that kind of difference, and almost no other moral disagreements have that as their source. Most other moral disagreements have as their ultimate source a difference in the rankings of the goods and evils or a difference in the estimates of the harmful and beneficial consequences of everyone knowing that a certain kind of violation is allowed. Although differing interpretations of the moral rules are usually based on differences in the rankings or in the estimates, sometimes custom or tradition will determine the interpretation. When there is a conflict among interpretations, an impartial rational person will interpret a moral rule in a way that she regards as resulting in the least amount of overall harm. There is an almost complete parallel in the procedures to be used when deciding what violation of a moral rule is justified and when deciding which of two competing interpretations of a moral rule to adopt.

People who have served on hospital ethics committees or on similar ethical decision-making bodies know how liberating it is to realize that on the most controversial questions, no one need be putting forward a wrong answer. This realization allows people to compromise without losing their moral integrity. It allows people to work together to find a solution that, while it may not completely satisfy anyone, satisfies everyone to some degree. It allows those in a subordinate decision making capacity to accept the decision of the person who has the final authority for making a decision, while at the same time allowing that person to acknowledge the acceptability of alternative views. It allows people to try to persuade each other, without implying that the other person is wrong or lacking in intellect or character.

These features are also of great importance in political theory. To hold the standard view that there is a unique correct answer to every moral question does not naturally incline one to support a democratic form of government. Unless a person holds that there are insuperable epistemological obstacles to finding out the correct answer, the natural result of holding the standard view is to favor a government of those who are most likely to know the correct answers to moral questions. However, if, on the issues about which there are likely to be disagreements, there are often no unique correct answers, then it is most natural for a person to endorse reaching a decision which is favored by the most people. Only a theory that holds that, especially on controversial matters, there is often no unique correct answer, provides a moral argument for democracy. Of course, any decision must be one that an impartial rational person could accept, but within these limits, there is often no best moral decision. A theory that does not provide a decision procedure that settles every moral problem allows for unresolvable moral disagreement. Such a theory might seem to be inferior to one that does provide such a decision procedure. However, more careful examination of both kinds of theories shows that the opposite is in fact true.

A complete moral theory should not be taken to be a theory that provides a unique correct answer to every moral question. Rather, a complete moral theory should explain and justify the overwhelming agreement on most moral matters, while at the same time explaining and justifying the limited disagreement on some of the most important moral matters. Moral theories that provide no explanation or justification for unresolvable moral disagreement are incomplete; those that claim there are no unresolvable moral disagreements are false. Beauchamp and Childress do say, “neither morality nor ethical theory has the resources to provide a single solution to every moral problem” (p. 24). However, they do not seem to realize that a complete moral theory must explain this fact, and must be helpful in pointing out the source of the disagreement. It is interesting that our theory fulfills the “eight conditions for an ethical theory” (pp. 338-40) that Beauchamp and Childress propose, far better than any other theory that they discuss, including their own.

A complete moral theory must not only provide analyses of the three concepts that are central to any account of morality, that of morality itself, and of impartiality and rationality, it must also show how these concepts are related to each other. A complete theory must also relate morality to human nature, making it clear why any beings having the essential features of human nature such as fallibility, rationality, and vulnerability would develop a public guide to conduct with all of the features of our common morality. Although common morality is a system, it does not remove the need for human judgment. It is true that common morality is systematic enough that a computer could be programmed so that, provided with the facts of the case, it always comes up with acceptable moral answers. However, another computer could be programmed differently and still always come up with acceptable but different answers. There is no computer program that can tell you which of the competing computer programs you should adopt.

Endnotes

3. Thomas Beauchamp and James Childress. Principles of Biomedical Ethics, 5th ed. (New York: Oxford University Press, 2001), 389. In a note, (note 9, p. 409) they acknowledge that we do provide a method for dealing with conflicts between rules, but not surprisingly, they criticize this method because it does not yield a unique answer to every conflict.


**Mental Maladies**

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The definition of mental disorder offered by DSM-III-R, DSM-IV, and DSM-IV-TR is in conflict with two quite distinct and opposing views. The first kind of definition, whose most prominent exponent is Christopher Boorse, provides an objective account of mental disorders solely in value-free scientific terms. The second kind of definition, which is represented by Tristam H. Engelhardt and Peter Sedgwick, defines mental disorder solely in society-based value terms. R. E. Kendell is talking about these two opposing views when he says the following: “The most fundamental issue, and also the most contentious one, is whether disease and illness are normative concepts based on value judgments, or whether they are value-free scientific terms; in other words, whether they are biomedical terms or sociopolitical ones.” Thus Kendell, in a paradigm of the fallacy of assumed equivalence, accepts the view that biomedical terms are value-free scientific terms and that normative concepts based on value judgments are sociopolitical terms. That some biomedical terms such as “disease” or “mental disorder” are objective value terms is not even considered as a possibility.

Jerome Wakefield, while agreeing with Kendell that value terms are sociopolitical, attempts to provide an account that reconciles the two opposing views of mental disorder that Kendell mentions. Against these two extreme accounts, Wakefield says, “I argue that disorder lies on the boundary between the given natural world and the constructed social world; a disorder exists when the failure of a person’s internal mechanisms to perform their functions as designed by nature impinges harmfully on the person’s well-being as defined by social values and meaning.” Wakefield defines a disorder as “a harmful dysfunction, wherein harmful is a value term based on social norms, and dysfunction is a scientific term referring to the failure of a mental mechanism to perform a natural function for which it was designed by evolution.” It is useful to examine Wakefield’s attempt at compromise in some detail as it illustrates the problems with both of the views that he is attempting to bring together.

The first problem involves the claim that a dysfunction is “the failure of a person’s internal mechanisms to perform their functions as designed by nature.” This view is reminiscent of Kant, who says, “In the natural constitution of an organized being, let us take it as a principle that in such a being no organ is to be found for any end unless it be the most fit and the best adapted for that end.” Kant simply assumes a teleological account of nature, derived from the view that God designed the best possible world. Wakefield’s account of dysfunctions as failures of a person’s internal mechanisms to perform their functions as designed by nature has the same characteristic. There is no reason to believe that every dysfunction is a failure of nature’s design. Evolution may not be quite as perfect as Wakefield takes it to be. A person is suffering from a dysfunction when she is suffering one of the harms mentioned in the definition of mental disorder in DSM-III-R, DSM IV, and DSM IV-TR, and there is no sustaining cause distinct from the person responsible for her suffering that harm. This is what the definition means by saying that the harm must be due to “a dysfunction in the person.” This would have been clearer if the DSM’s definition explicitly included the concept of a distinct sustaining cause.

Although Wakefield claims that there is a dysfunction only if there is a “failure of a person’s internal mechanisms to perform their functions as designed by nature,” he actually relies on there being no distinct sustaining cause as indicating a dysfunction. He says, “The fact that in Post-Traumatic Stress Disorder (PTSD) the person’s coping mechanisms often fail to bring the person back to functional equilibrium months and even years after the danger is gone, and that PTSD reactions are dramatically out of proportion to the actual posttraumatic danger, suggests that the response is indeed independent of any environmental maintaining cause and therefore is a dysfunction.” It is from the fact that there is no “environmental maintaining cause” that he infers that the person’s distress is due to a dysfunction. He does not and cannot know directly that there is a “failure of a person’s internal mechanisms to perform their functions as designed by nature.” The claim that a dysfunction is a failure of nature’s design is often unverifiable. Perhaps nature designed people to deteriorate and die, in order to allow for the species to develop. Regardless of nature’s design, if a person is suffering or at a significantly increased risk of suffering death, pain, disability, or an important loss of freedom or pleasure, and there is no distinct sustaining cause, he has a dysfunction.

It is significant that Wakefield never mentions conditions that significantly increase the risk of suffering harm such as very high blood pressure as a disorder for, on his view, until there is a failure of nature’s design, there is no dysfunction.

**Societal Values and the Definition of Mental Disorder**

Wakefield’s second problem is his acceptance of the common view of social scientists that values are constructed by particular societies. By accepting this account, he opens the door to the kind of relativity that the definitions of mental disorder in DSM-III-R, DSM-IV, and DSM-IV-TR were designed to close. He does not seem to realize that if harms are determined primarily by social norms, then this opens the door to the criticism of psychiatry as primarily enforcing social norms. Wakefield claims, “The requirement that there be harm also accounts for why albinism, reversal of heart position, and fused toes are not considered disorders even though each results from a breakdown in the way some mechanism is designed to function.” Since Wakefield claims that albinism is a failure of nature’s design, if a particular society negatively evaluates albinism, then it is a disorder in that society, but not a disorder in a society that does not negatively evaluate it. A person can cease to have a disorder simply by moving from one society to the other.

Also, if homosexuality and sexual deviations are taken as involving a breakdown in the way some mechanism is designed to function, homosexuality and other sexual deviations would be mental disorders in those societies where they are negatively evaluated and not in those societies where they are not so evaluated. His suggested definition would reverse the progress that was made in DSM-III-R, DSM-IV, and DSM-IV-TR, definition, when “conflicts that are primarily between the individual and society” were explicitly ruled out as a criterion of mental disorder. Only traits that would result in conflict with all societies count as a dysfunction in the person. This is the way in which
the additional criterion that was added to the list of criteria for the paraphilias in DSM-IV should be understood. “The fantasies, sexual urges, or behaviors cause clinically significant distress or impairment in social, occupational, or other important areas of functioning.”

Wakefield’s acceptance of the common view of social scientists, that values are constructed by particular societies, is what leads him to think that harm cannot be defined in universal terms. However, as we showed in Chapter 2, it is universally true that, in the absence of reasons to hold otherwise, rational persons in every society regard death, pain, disability, and loss of freedom or pleasure, as harms. No person who is considered rational wants to suffer any of these harms unless he has some belief that he or someone else will avoid what is considered by a significant number of persons as either a greater harm, or a compensating benefit, such as greater consciousness, ability, freedom, or pleasure. The universality of these harms and benefits is shown by the fact that nothing counts as a disorder unless it involves one of these harms or a significantly increased risk of suffering them, and nothing counts as a punishment unless it involves the infliction of one of these harms.10

The agreement of rational persons in all societies about the universality of the basic harms is extremely important for it establishes the objectivity of the concept of a disorder. Disorders, mental or physical, are conditions that are associated with suffering distress or disability or a significantly increased risk of suffering death, pain, disability, or an important loss of freedom or pleasure. Mental disorders, properly understood, like physical disorders, are not merely labels for conditions that some culture or society has arbitrarily picked out for special treatment.11 Mental disorders are conditions that no rational person in any society wants himself, or anyone he cares for, to suffer, unless there is some compensating benefit.

It is not a symptom of a mental disorder to be distressed on discovering that one has a physical disorder, e.g., cancer, because the physical disorder counts as an event in the world just as the death of a loved one and one’s distress is an expectable and culturally sanctioned response to this situation. However, if the distress goes beyond an expectable and culturally sanctioned response to a particular situation, then one may be suffering a mental disorder that the physical disorder, just like other unfortunate events in the world, may have played a significant role in causing. What counts as an expectable and culturally sanctioned response to a particular event often differs from society to society and from culture to culture within large multi-cultural societies like the United States. But suffering distress or disability or a significantly increased risk of suffering death, pain, disability, or an important loss of freedom, is a necessary feature of any disorder, mental or physical.

The fact that it is primarily on the basis of their symptoms that mental disorders differ from physical disorders makes it clear that “Neither deviant behavior (e.g., political, religious, or sexual) nor conflicts that are primarily between the individual and society are mental disorders unless the deviance or conflict is a symptom of a dysfunction in the person.” However, if the conflicts between a person and society are such that they would occur in all societies, this is a symptom of a dysfunction in the person. Although deviance, by itself, is not sufficient to count as a disorder, some deviance seems to be so closely related to distress or disability or a significantly increased risk of suffering death, pain, disability, or an important loss of freedom or pleasure, that it is often classified as a disorder. Thus having a third eye in one’s head might actually give one greater visual ability than those having the normal number of eyes. Nonetheless, normal human responses to this kind of deviance may so regularly involve either pain or an important loss of freedom or pleasure that the deviance itself is regarded as a physical disorder. Similarly, normal human responses to some deviant behavior, e.g., sexual intercourse with corpses, may normally call forth such a universal negative human response that the condition is itself regarded as a mental disorder. However, for the reactions of others to any deviance, either physical or mental, to make a deviant condition count as a disorder, the reactions must be universal human responses, not merely the response of those in a particular society.

Although the DSM-III, DSM IV, and DSM-IV-TR definition of mental disorder can be improved, it is far superior to any of the alternatives, including Wakefield’s, that have been proposed to replace it. Its major achievement is its acceptance of universal values, so that values can be included in the definition of a mental disorder without thereby making a disorder relative to each individual society. That is a significant achievement.

Endnotes


3. Wakefield, 1992b. This quote is from the abstract that precedes the paper. Wakefield’s view is listed as a mixed model by Christian Perring in his article “Mental Illness” for the Stanford Online Encyclopedia of Philosophy. We have benefited from reading this article and from comments by Perring. However, we do not agree with Perring on several points.

4. It seems that on this account of dysfunction, dyslexia is not a disorder, because it is unlikely that nature designed an internal mechanism to perform the function of distinguishing between b’s and d’s.


7. See op cit., p. 233, where there is no mention of increased risk of suffering the universal harms.


9. DSM-IV (1994), pp. 523-32. In DSM-III-R, this criterion was preceeded the paper. Wakefield’s view is listed as a mixed model by Christian Perring in his article “Mental Illness” for the Stanford Online Encyclopedia of Philosophy. We have benefited from reading this article and from comments by Perring. However, we do not agree with Perring on several points.

11. Appendix I of DSM-IV-TR (pp.897-903) contains a Glossary of Culture Bound Syndromes, but all of these that are considered disorders also involve distress or disability or a significantly increased risk of suffering death, pain, disability, or an important loss of freedom. Wakefield ("The Concept of Mental Disorder: On the Boundary between Biological Facts and Social Values," American Psychologist, 47, page 380) says, "this list might be considered to be an operationalized approximation to the requirement that there must be harm." That he does not realize that this is a list of universal harms, not merely negative evaluations based on social norms, is confirmed by his statement on the following page. "Although a typology of harms such as that provided by DSM-III-R is useful, it should not be forgotten that...the underlying reason these effects are relevant to disorder is that they are negative and this evaluative element is fundamental to our judgments about disorder." Wakefield does not realize that this list of harms provides a list of objective harms that are not dependent on the evaluative judgments of particular societies.

ANNOUNCEMENTS

Sullivan Scholars Program Announced
The Neiswanger Institute of Loyola University Chicago Stritch School of Medicine is pleased to announce the Louis W. Sullivan, M.D., Scholars Program in Bioethics and Health Policy. This unique program provides a half-tuition scholarship in the online MA in Bioethics and Health Policy to qualified under-represented minority faculty from colleges and universities around the nation. Sullivan Scholars enhance their career development through study and collaboration with other scholars and health-care professionals from across the nation. A notable feature of the program is that the tuition paid by these scholars is earmarked for the minority scholarship fund for medical students of the Stritch School of Medicine. The Sullivan Scholars program thereby contributes to minority representation in both bioethics and medicine. Two scholarships will be available annually. It is anticipated the scholars will also have occasional opportunity to consult with Dr. Sullivan. For more information e-mail onlinemasters@lumc.edu or visit the website at http://bioethics.lumc.edu

Conferences
April 6 - 8, 2006
Ethics and the Business of Biomedicine
Knoxville, TN

April 18 - 19, 2006
Decision Making in Age of Mistrust-Rethinking Autonomy & Justice
Atlanta, GA

April 26 - 28, 2006
11th European Forum on Quality Improvement in Health Care
Prague

May 1, 2006
The Manuel Velasco-Suarez Award in Bioethics 2006
Washington, D.C.

June 4 - 7, 2006
4th International DNA Sampling Conference: “Genomics & Public Health”
Montreal

June 12 - 14, 2006
2nd Annual International Summit on Redesigning Hospital Care
Atlanta, GA

June 12 - 16, 2006
8th Annual Ethical Issues in International Health Research
Boston, MA

June 26, 2006 - July 7, 2006
Technologizing Humanity or Humanizing Technology?
Rome

July 28, 2006
Creative Ethical Problem Solving in Human Research
Oakland, CA

September 20 - 22, 2006
6th International Conference on Priorities in Health Care
Toronto

September 28 - 30, 2006
New Pathways for European Bioethics
Leuven, BEL

ASBH 8th Annual Meeting
“Challenging Voices”
October 26 - 29, 2006
Marriott Denver City Center
Denver, CO