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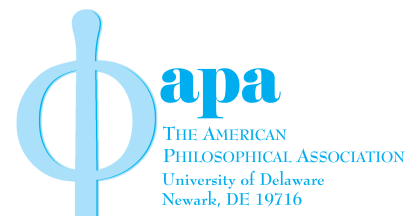
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FROM THE EDITORS

Once again, the *Newsletter on Philosophy and Medicine* is pleased to bring our readers an issue chock full of interesting papers. Presentations from the Pacific Division session on "Research Ethics and Human Vulnerability" sponsored by the Committee on Philosophy and Medicine are presented here as a group of papers. This collection of papers by Robert E. Goodin, Kenneth Kipnis, and Dorothy E. Vawter and Karen G. Gervais forms an important contribution to the literature on vulnerability in research. Also in this issue are papers on presidential privacy, race and ethnicity, and gender. These papers by Timothy F. Murphy, John R. Stone, and Jennifer A. Parks raise timely and challenging issues for bioethics in unusual terms. In sum, this issue offers a particularly fresh and engaging collection thoughtful papers on interesting issues.

Robert E. Goodin's piece on "Vulnerable Research Subjects" discusses two senses of vulnerability, one as a reason for action, another as a disqualifying condition. Goodin explains how both concepts factor into our thinking about biomedical research as well as medical treatment. He also discusses how subject vulnerability was transformed into the research ethics focus on informed consent and how the prominence of that principle has obscured other important concerns in the ethical conduct of research. Instead of focusing so closely on informed consent, Goodin proposes the concept of "autonomy interests" as a guide for research involving subjects who cannot provide informed consent.

In his paper on "Vulnerability in Research Subjects," Kenneth Kipnis provides a novel approach to thinking about research subjects who are vulnerable. He explains seven different ways in which research subjects may be vulnerable. Kipnis suggests that rather than addressing specific subpopulations, rules for the ethical conduct of research should be sensitive to the varieties of vulnerability and focus on compensating strategies to address how the individual subjects may be vulnerable.

Dorothy E. Vawter and Karen G. Gervais challenge Kipnis's approach in their paper "Reflections on Kipnis' Concept of Medical Vulnerability." Although they acknowledge that some of Kipnis's suggestions are already incorporated into study design, they see others as aspirational standards. Furthermore, they object to some of Kipnis's suggestions as subject inducements plans and where Kipnis finds subjects to be vulnerable because of their impaired ability to comprehend risks and benefits, Vawter and Gervais argue that measures should be taken to minimize the distorting influence of the therapeutic misconception rather than providing compensation. Their most pointed criticism is that Kipnis's calls for the maximization of therapeutic benefit undermines the crucial research agenda.

Timothy F. Murphy takes us off to another subject in his discussion of "Medical Confidentiality and Presidential Families." This is a timely piece that addresses questions raised about the Reagan family's lack of open discussion about details of President Reagan's illness and their treatment decisions in the period after he lost decisional capacity. Murphy offers several important distinctions to help us address the scope of privacy and access to information about public figures.

John R. Stone raises the white issue in his paper on "Race/Ethnicity, Health Disparities, and Bioethics." In his words, philosophy and bioethics are certainly "white-dominated" fields. In his paper, Stone explains how seeing issues of racial and ethnic disparities can have a different significance when seen through the eyes of whites or the eyes of people from groups that have suffered health disparities and who have been the historical subjects of discrimination. Stone identifies structural and policy issues that whites may overlook and discusses how sensitivity to racism and ethnic bias can make a difference in our analysis and approach to health disparities.

In her paper, "A Call for Gender Equity in Medical Tort Reform," Jennifer A. Parks discusses President Bush's proposal to limit monetary awards for pain and suffering in medical tort cases. Parks takes the silicone breast implant cases as her illustrative example and uses it to discuss the justice of the Bush plan. She presents a compelling case that Bush's petition encourages corporate negligence, places undue burdens on plaintiffs, and disadvantages women.

We want to be able to provide our readers with similarly rich issues in the future. So, we remind you to please send along your announcements, letters, papers, case analyses, poetry, and stories. Please feel free to volunteer a book review. Your contributions and queries should be sent to Rosamond or Mark at the addresses below. Please include your phone and fax numbers and email address.

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FROM THE CHAIR

Philosophical Reflection and the President's Council on Bioethics

David DeGrazia

George Washington University

When President Bush appointed the President's Council on Bioethics in January, 2002, some within the bioethics community expressed dismay about the PCB's membership. The new committee was long on conservative credentials and short on expertise in bioethics, according to the critics. How could the PCB, they rhetorically asked, represent expertise in bioethics when only a minority of its members could boast scholarly credentials in this field? Weren't the appointments more a reflection of the President's conservative agenda than a reflection of the face of American bioethics? Representing such concerns, Jonathan Moreno—a well-respected philosopher-bioethicist at the University of Virginia and one of the more liberal scholars invited to serve—rejected the invitation. Charges of a political agenda driving committee membership resurfaced last year when two PCB members, Elizabeth Blackburn and William May, were quietly dismissed and replaced by scholars holding views more in line with Chair Leon Kass and the President himself.

Behind Kass's energetic leadership, the PCB has so far published five reports: *Human Cloning and Human Dignity* (July 2002), *Beyond Therapy: Biotechnology and the Pursuit of Happiness* (October 2003), *Being Human: Readings from the President's Council on Bioethics* (December 2003), *Monitoring Stem Cell Research* (January 2004), and *Reproduction and Responsibility: The Regulation of New Biotechnologies* (March 2004). Having read three of these publications, I have found them well-written, erudite, very intelligent, and relatively courageous in exploring difficult ethical terrain and frequently challenging liberal "received wisdom" in bioethics. Coming from me, this is no trivial compliment because my moral judgments tend to be more in line with this liberal mainstream than with the President and PCB majority opinion. Even those far more critical of the PCB than I am must acknowledge that its work is addressing some of the most important forward-looking bioethical issues of our day. Apparently agreeing with this sentiment, the American Society for Bioethics and Humanities has set up a panel, consisting mostly of PCB members, to discuss the report *Beyond Therapy* in the ASBH's annual meeting next October.

While biotechnological enhancement is an important, timely issue, embryonic stem cell research (ESCR) is, if anything, even more pressing. After Ronald Reagan's death last June, following years of suffering from Alzheimer's disease—which many researchers believe ESCR holds special promise in treating—Nancy Reagan reinvigorated political discussion by publicly calling upon President Bush to relax restrictions he imposed on ESCR in the U.S. In an effort to draw a principled, pro-life line that was reasonably responsive to consequentialist concerns about research progress, Bush had on August 9, 2001 issued an executive order restricting federal funding for ESCR to research using stem cell lines created prior to the time of his order; no further embryos, not even those left over in fertility clinics and destined to disposal, could be "sacrificed" for federally funded research. Will Bush revise his position and, with it, American public policy? More importantly from an ethical standpoint, should he?

Confident in philosophy's ability to illuminate such difficult problems as those identified here, the APA's Committee on Medicine and Philosophy has established a panel entitled "The President's Council on Bioethics: Political Legitimacy and the Report on Stem Cell Research," for the upcoming Eastern Division Meeting in Boston. Alfonso Gomez-Lobo of Georgetown University, a member of the President's Council who has recently published on ESCR, will open by discussing ethical issues raised by this research—presenting his own views rather than attempting to speak for the entire PCB. Hilary Bok of Johns Hopkins University, a respectful critic of the PCB report in question, will challenge some of its reasoning. Leslie Francis, of the University of Utah, and Timothy Murphy, of the University of Illinois in Chicago, will take up questions concerning the PCB's political legitimacy and representation of American bioethics in addressing such issues as ESCR.

The Committee on Medicine and Philosophy looks forward to an open, vigorous yet respectful, and rewarding discussion of these issues by the panelists and members of the audience.

OBITUARIES

John Fletcher, In Memoriam

Franklin G. Miller, Ph.D.

National Institute of Health

John Fletcher was one of the pioneers of bioethics, who helped create the way of thinking and the set of practices that we call bioethics. His reach within bioethics was wide and deep. John created an institutional presence for bioethics within the NIH Clinical Center—a daunting task which he pursued for 10 years, starting in 1977. Then he founded and developed a leading bioethics center at the University of Virginia. Perhaps his most important contributions were in scholarship relating to the ethics of reproductive technologies, conceptualizing and editing one of the major textbooks in clinical ethics, and zealously promoting hospital ethics programs, including ethics committees, ethics consultation services, and ethics education.

John carried his religious vocation into the world of bioethics, leading the way for others and building communities of professionals dedicated to promoting moral reflection and moral conduct in the areas of medical research and medical care. What was it about John that moved people to share his passion for bioethics? It wasn't his scholarship, though he was a very productive and influential scholar. It wasn't his teaching, though John was a talented teacher. It was the strength of his personality, which had a gravitational force that drew others into his orbit and to the shared vocation of bioethics. I certainly would never have come to bioethics as a career at age 42 had I not been drawn in by the force of John's personality, and by his dedication and commitment to make a difference in the climate of clinical medicine and research. John's greatest strengths lay in reaching out to others to encourage them to join the bioethics movement and to contribute as teachers, ethics consultants, ethics committee members, and as scholars. He was a valued mentor to many bioethicists and clinicians interested in ethical issues.

For those of us in the second generation of bioethicists, it is hard to imagine what it was like to bring bioethics into the

clinical setting. In the words of David Rothman, John Fletcher was one of the “strangers at the bedside” who opened up the medical world to scrutiny from a moral perspective grounded in the rights of patients and research subjects. He made it less strange for those who followed in his footsteps.

John, I believe, would not want us to look back on his life with rose-colored glasses. Like all of us, he had his weaknesses alongside his strengths. As Kant famously said, “Out of the crooked timber of humanity, nothing straight was ever made.” John had a keen sense of his own fallibility. He learned how to navigate as an ethics consultant, called in to help resolve emotionally charged moral disputes, by jumping in, trusting his judgment, and making mistakes. Reflecting on mistakes was an opportunity for learning how to do it better. John invited criticism; he listened to it, and took it to heart. John liked to quote a saying of Paul Ramsey, another bioethics pioneer with whom he often disagreed, “The room for improvement is the biggest room in the house.”

John will not be forgotten by those who had the good fortune of feeling the gravitational force of his charismatic personality and witnessing his visionary leadership.

James Rachels, In Memorial

Gregory Pence

University of Alabama at Birmingham

James Rachels died from cancer on September 5, 2003 at age 62. A native of Georgia, Jim was graduated from Mercer University and earned his Ph.D. at the University of North Carolina. He then taught at Duke University, the University of Richmond, and on the graduate faculties of both New York University and the University of Miami. At NYU in the early 1970s, he was associated with a small group of philosophers who started the seminal New York chapter of the Society for Philosophy and Public Affairs, a group that included Tom Nagel and visiting scholars Peter Singer and Derek Parfit. In 1977, Jim became chair of Philosophy at the University of Alabama at Birmingham, rising three years later to become Dean of Arts & Humanities from 1978-1983, then had a one-year stint as acting Academic Vice President, after which he became University Professor.

Jim had a special talent for elucidating complex philosophical issues in deceptively clear language. His early book, *Moral Problems*, was one of the first anthologies in the new field of applied ethics and in its first three years sold over a hundred thousand copies. According to his publisher, McGraw-Hill, his most well known book, *The Elements of Moral Philosophy* this year will sell more copies than any other philosophy text, and will be used in one third of ethics classes in North America. McGraw-Hill will posthumously publish Jim’s newly completed *Introduction to Philosophy*.

Jim’s paper, “Active and Passive Euthanasia,” was the first piece published by a moral philosopher in the *New England Journal of Medicine* (1975). Today it is still one of the most-reprinted articles in ethics, having been reprinted to date over 300 times. As the *New York Times* said in its extensive obituary, the piece “ignited” a debate over euthanasia, and “helped start an applied ethics movement in philosophy.” This seminal piece, along with others by Judith Thomson and Peter Singer, gave philosophers issues to talk about in class that had philosophical heft.

His book *The End of Life: Morality and Euthanasia* (Oxford, 1986) defended humane, humanistic treatment of

standards of death and dying. His *Created from Animals* argued that modern ethics should pay more attention to similarities between human and non-human animals, rather than rigidly separate the two. In *Can Ethics Provide Answers?* (1997), he reprinted a dozen of his 60 essays from many journals, ones he thought would stand the test of time. He also edited seven books and served as a referee for several academic journals.

Although his writings defended radical positions, in person he was neither confrontational nor an activist, preferring to let his writings do this work. More than anything else, he loved doing philosophy and being a philosopher. In the last months of his life and on the last day of his life, he was writing philosophy, finishing last bits and pieces. Near his last day, he told his sons that, for the first time in his life, he had no unfinished projects in philosophy.

He is survived by his wife of forty years, Carol, and his two sons, David, an English professor at VMI, and Stuart, a philosophy professor at the University of Alabama in Tuscaloosa, his two grandchildren, and in Georgia, his parents and two sisters.

The UAB Philosophy has started the Rachels Visiting Scholar Endowment Fund to honor Jim’s life. Contributions for it may be sent to: Philosophy, 900 13th Street South, Birmingham, AL 35294-1260.

ARTICLES

Vulnerable Research Subjects*

Robert E. Goodin

Australian National University

My concern here is with the vulnerabilities of people who are “objects of medical interventions.” I mean for that term to extend to “patients” in the case of therapeutic interventions as well as to “subjects” in the case of experimental interventions. The latter are the official focus of my discussion, but reflecting on cognate cases of vulnerable patients in therapeutic settings sheds useful light on the case of vulnerable research subjects

It is the vulnerability of agents to other agents that most concerns me here (although I shall also, of course, be tangentially concerned with the various *conditions* that make them vulnerable to one another¹). In general, one agent is “vulnerable” to another insofar as the interests of the former are sensitive to the actions and choices of the latter.² In a therapeutic setting, the patient’s vulnerability is largely (if not exclusively) to the attending physician. In an experimental setting, the subject’s vulnerability is (again, largely if not exclusively) to the researcher.

I. Vulnerability’s Two Faces

Considerations of vulnerability might enter into bioethical reflections in two quite different ways.

First is a broadly “consequentialistic” way, as in Goodin’s *Protecting the Vulnerable*.³ By definition, if Sam is particularly vulnerable to Dr. Sue, then Sam’s interests are highly sensitive to Dr. Sue’s actions and choices. It therefore automatically follows that for any ethical theory which attaches moral importance to promoting people’s interests, there is a moral

reason for Dr. Sue to be particularly attentive to how her actions and choices will impact Sam's interests. (Of course that reason is defeasible: there might be other stronger reasons for Dr. Sue to do something else.) That moral reason is stronger the more strongly—and, we might add, the more uniquely—Dr. Sue's actions and choices are capable of affecting Sam's interests.

On this broadly "consequentialistic" account, Sam's vulnerability (the potential impact of Dr. Sue's actions and choices on Sam's interests) is a reason for Dr. Sue to do something. Perhaps we might characterize that as a "responsibility" (or even perhaps a "duty"), derived from those consequentialistic considerations concerning Sam's vulnerability to her. But for now, we can just leave it, more non-committally, as a "moral reason."

A second way in which "vulnerability" might figure is as an exception or "disqualifying condition" within a broadly "deontological" conception of bioethics. On this model, we must above all respect the human dignity and moral autonomy of those with whom we deal. For medical practitioners and researchers, this is done by (among other things) securing "informed consent" from patients or subjects for procedures performed on them.⁴ Of course, there are many ways of telling a deontological tale. But because my concern here is with how vulnerability enters the picture, I shall focus on what I will call a "hard-line" version of the deontological ethic that makes informed consent a necessary if not sufficient condition of permissible medical interventions.⁵

"Vulnerability" enters into that sort of a consent-based deontological model as a disqualifying condition. "Vulnerabilities" of various sorts render agents incapable of giving meaningful consent to having those medical or experimental procedures performed on them. In the limiting case, vulnerable agents might not be able to consent at all—their vulnerability might be such as to deprive them of agency altogether. Here, however, I am going to focus on less extreme cases. These are cases in which vulnerable agents are still capable of giving what seems to be consent, but in which we are unsure of the moral value of that consent. The worry is that their vulnerability renders their putative consent "tainted," rather like a coerced confession in a criminal court or an agreement obtained by force or fraud in the law of torts. Where agents are sufficiently vulnerable, their putative consent might count for naught.⁶

II. If Not Consent, What?

What follows when someone is not capable of meaningfully consenting to, or meaningfully withholding consent from, some intervention?

Well, within a hard-line deontological ethic in which consent is the *only* right-maker, the upshot would be clear. If we do not have the permission of the person (or his or her authorized agent) to intervene in ways impinging his or her moral prerogatives, then we have no right to so intervene. This is as true of someone whose capacity to consent is compromised as it is of someone who is capable of consenting but who willfully withholds consent: in neither case do we have any right to so intervene, if consent is the *only* right-maker. *Why* a moral agent does not consent does not matter; the sheer absence of consent is all that matters in morally blocking our action.

I hasten to add that this is a much harder-line deontological ethic than is embodied in any actual code of medical ethics. It seems so extreme as to preclude surrogate decisions for incapacitated patients, by anyone except perhaps their legally authorized representatives.⁷ In that and many other less extreme ways, this hard-line deontological ethic is very unlike

any actual code of medical ethics operative anywhere in the world.⁸ Still, when excavating the true moral groundings for the ethical codes operative among us, it pays to begin by first exploring the limiting cases like this.

This hard-line deontological ethic that treats consent as the only right-maker is especially interesting to explore in the context of the ethics of human experimentation, because at first brush, that looks like the ethic dominating thinking. The first "Directive for Human Experimentation" embodied in the Code laid down by the Nuremberg Tribunal specifies that:

The voluntary consent of the human subject is absolutely essential. This means that the person involved should have legal capacity to give consent; should be so situated as to be able to exercise free power of choice, without the intervention of any element of force, fraud, deceit, duress, over-reaching, or other ulterior form of constraint or coercion; and should have sufficient knowledge and comprehension of the elements of the subject matter involved as to enable him to make an understanding and enlightened decision.⁹

In short, at least at first brush: No consent, no experiment—on pain of something akin to practicing Nazi medicine. And insofar as the notion of vulnerability points to conditions invalidating consent, it thus provides what Ken Kipnis calls "a checklist of circumstances that...can invalidate the permissibility of research."¹⁰

But of course experimental settings are hardly the only ones in which doctors find themselves confronted with people who are vulnerable. Let us shift our focus to a therapeutic setting—a comatose patient who will die without urgent surgery, let's say. There, "no consent, no intervention" would not be a sensible policy; certainly it is not the practice generally adopted in Emergency Rooms. There, after quickly checking the patient's wallet and trying to contact the next of kin for instructions, the attending physician properly proceeds with whatever treatment "best medical practice" dictates in the circumstances— "as if" s/he had the patient's informed consent, even though s/he does not.

So too, upon reflection, should the experimenter. Indeed, the provisions of the *US Code of Federal Regulations* governing "Informed Consent of Human Subjects" now makes explicit provision for granting an "exception from informed consent requirements for emergency research."¹¹ In certain tightly circumscribed conditions, experimental procedures that "hold out the prospect of direct benefit to the subjects" may be permitted on people from whom consent could not possibly be obtained ahead of time. One example was an experiment locating defibrillators in airports, to be used by laypersons on people having heart attacks before medics arrived, to see if that helped save lives: it was accepted by those authorizing that experiment that it was simply infeasible to obtain reliably informed consent from people in the midst of a heart attack; and since there was good reason to think that heart attack victims could benefit from those interventions, the experiment was authorized despite the fact that informed consent could not be obtained.¹²

Our concern here is with a medical researcher confronted with vulnerable subjects, and our question is, "What, then, follows from the fact that some subjects are "vulnerable" in ways that undermine their capacity to give or withhold meaningful consent for experiments to be practiced upon them?" The proper conclusion is not that we ought necessarily exclude them from our experiments—any more than in the "waived consent" cases we should exclude those who could

benefit substantially from participation in the experiments, just because they cannot give informed consent. Rather, what follows is that we should apply “special scrutiny” to the conditions of their participation. Note, for example, the phrasing of the World Medical Association’s Helsinki Declaration: “When obtaining informed consent for the research project the physician should be *particularly cautious* if the subject is in a dependent relationship to him or her or may consent under duress.”¹³ Just as Emergency Room physicians performing emergency procedures on comatose patients are supposed to think in terms of what those patients would “have good reason” to consent to, so too ought experimenters confronted with subjects whose seeming “consent” is compromised by their vulnerability pay special attention to whether those subjects would “have good reason” to consent, were it not for those vulnerabilities.¹⁴

This is sometimes expressed in terms of “hypothetical consent.” That can be an evocative way of calling to mind the reasons people might have for consenting. But what it provides us with is a window onto the agent’s reasons, not a warrant rooted in the agent’s will. Hypothetical consent is no kind of consent at all, as generations of students have been rightly taught to scoff when confronted with “just so” stories of a “social contract.”¹⁵ If the hard-line deontological model is correct, and consent is the only possible right-maker for interventions of this sort, then it is *actual* consent that is morally required to do the trick.

If the prime moral directive is to respect the other’s moral agency and moral autonomy, then actual rather than merely hypothetical consent is the only moral warrant that there can be for intervening into the sphere of someone else’s proper moral prerogatives. For us to acquire a right to operate on (or experiment on) people whose actual consent is morally questionable, we have to move away from that hard-line deontological model toward a more consequentialistic one, which takes due account of vulnerabilities in its own peculiar way.

III. Consent in Consequential Context

I take it that neither of the polar forms of ethics, deontological or consequentialistic, is altogether tenable in a health-care context. A hard-line deontological ethic would, as I have just been arguing, deprive us of the ability to treat emergency room patients clearly in need of medical attention but incapable of consenting to the procedures. Conversely, a hard-line consequentialistic ethic might risk turning us into Nazi physicians, practicing procedures on people who clearly (but, we have good medical reason to believe, wrongly) refuse to consent.

In searching for a hybrid, my own inclination is to build on consequentialist foundations, grafting consent-based considerations onto that. Here, in brief, is the strategy I would propose.

Recall the consequentialist story I told above, in which Sam’s vulnerability to the actions and choices of Dr. Sue gave moral reasons for Dr. Sue to be particularly solicitous of Sam’s interests in her actions and choices. All we need to get an element of consent into the picture is to recall that among those interests of which Dr. Sue is supposed to be solicitous are Sam’s “autonomy interests.” Sam, like all moral agents, has an interest in being and being seen to be a self-governing agent capable of embracing and acting on reasons of his own. The reason Dr. Sue should, where possible, seek Sam’s consent to any procedure—even where she is sure it is one that best promotes all of Sam’s *other* interests—is that securing Sam’s consent is the only way also to protect his *autonomy* interests.

This way of building autonomy interests in, alongside Sam’s other interests, has several advantages. It explains, in a way the hard-line deontological model cannot, why it might be all right to perform procedures on people incapable of consenting or whose consent is tainted by vulnerabilities of various sorts (their autonomy interests are not actually being overridden, insofar as they are not actually in play). It explains, perhaps better than any plausible variation on the hard-line deontological model can explain, why it is wrong for physicians to help kill anyone who genuinely wants to die, without further enquiries.¹⁶ (Presumably even those of us who would approve of physician-assisted suicide would ordinarily want the physician to ensure, for example, that the patient had a terminal illness rather than was merely “tired of living” or just was having a bad day.)

There are many details left to be worked out with that hybrid model, to be sure.¹⁷ I do not want to belabour them here, however. Instead, I want merely to point out that something like that sort of hybrid is—contrary to what seems to be the common supposition—what actually lies at the heart of contemporary strictures surrounding the ethics of human experimentation.

What the bioethics profession generally seems to remember as the rule of “the Nuremberg Code” is the first Directive, quoted earlier—the one that says “the voluntary consent of the human subject is absolutely essential.” That is why we hear, so often, that “the Nuremberg Code’s foundational concern” is with “the concept of consent.”¹⁸

That consent-based principle was undoubtedly of signal importance to the Nuremberg Tribunal. After all, they listed that as their first Directive, and they elaborated on it at far greater length than any other item on their list. But what seems often to be forgotten is that the Nuremberg Tribunal did go on to list nine *further* Directives, only one of which has anything to do with the consent of the research subject.¹⁹

The other forgotten eight Directives of the Nuremberg Tribunal that are more consequentialistic in form are these²⁰:

1. The experiment should be such as to yield fruitful results for the good of society, unprocurable by other methods or means of study...
2. The experiment should be so designed and based on the results of animal experimentation and a knowledge of the natural history of the disease or other problem under study that the anticipated results will justify the performance of the experiment.
3. The experiment should be so conducted as to avoid all unnecessary physical and mental suffering and injury.
4. No experiment should be conducted where there is a priori reason to believe that death or disabling injury will occur...
5. The degree of risk to be taken should never exceed that determined by the humanitarian importance of the problem to be solved by the experiment.
6. Proper preparations should be made and adequate facilities provided to protect the experimental subject against even remote possibilities of injury, disability, or death.
7. The experiment should be conducted only by scientifically qualified persons. The highest degree of skill and care should be required through all stages of the experiment of those who conduct or engage in the experiment.

...

8. During the course of the experiment the scientist in charge must be prepared to terminate the experiment at any stage, if he has probable cause to believe... that a continuation of the experiment is likely to result in injury, disability, or death to the experimental subject.²¹

Thus, while consent is of signal importance (as per Directive 1), consent is supposed to come only after a whole raft of consequential requirements have already been met.²² Essential though people's consent may be to the ethical legitimacy of experimenting on them, those other background conditions are also equally essential. Consent is capable of transforming illegitimate experiments into legitimate ones, only when it is given against the background of all those other consequential conditions having also been satisfied.

Upon reflection, this is surely unsurprising. After all, we would not let a surgeon perform an operation—even with the patient's consent—unless there was some reason to think that the operation would do some good. (Presumably even with purely cosmetic surgery, we have to have good grounds for thinking that it will succeed, at least on its own terms, for it to be justifiable.) By the same token, we would not let an experimenter perform an experiment, even with the subject's consent, if there were not evidence from animal experiments and so forth to suggest that the experiment might succeed. A subject's fully-informed consent to experimental procedures that are unnecessary, incompetent, or gratuitously dangerous morally counts for naught. That—as much as the better-remembered principle that “the voluntary consent of the human subject is absolutely essential”—is the law of Nuremberg.

Of course, we would not want to proceed without first (if possible) obtaining the consent of the patient or subject, as well. We do not want to operate or experiment on unwilling subjects. But consequentialistic-style considerations constitute a prior hurdle. We do not want to perform operations or experiments on people without good reason to think that they will work, either.

Why then, we might ask, is the issue about “consent” so much better remembered among medical ethicists? Well, recall for whom medical ethicists are principally writing: people at the medical coalface, which is to say, practitioners at the bedside. This is evident in, for example, the AMA's “Principles of Medical Ethics”: well over half of the nine guiding principles clearly pertain to relations between the doctor and his or her own specific patients. It is all the more evident in the Physician's Oath prescribed by the World Medical Association's “Declaration of Geneva,” which has the physician avowing that “the health of my patient will be my first consideration.”²³

From the point of view of medical practitioners at the bedside—face-to-face with patient in therapeutic settings or subjects in experimental ones—the belief that “voluntary consent is absolutely essential” is indeed the thought that they *should* hold most firmly in mind. That is not because those other Nuremberg Directives (and their therapeutic equivalents) do not matter. It is merely because that is not *where* they matter. The bedside is not the place to meet those other requirements. They should have been (indeed, they *have* to have been) taken care of elsewhere, in planning the experiment or treatment regime.

The bit of the Nuremberg Code that is uniquely the responsibility of a physician who is face-to-face with a patient or experimental subject is the bit about obtaining “voluntary consent.” And given that it is practitioners at the bedside to whom codes of medical ethics are principally addressed, it is

only right that that principle should be accorded heavy emphasis—heavier emphasis than it would be, if we were addressing instead (or even equally) planners of health care systems or designers of medical experiments.

IV. Vulnerabilities against Vulnerabilities

When cashing out our morals in the currency of vulnerability, it is important to remember that those research subjects who we nervously deem “vulnerable” in ways that might compromise their consent to the experiment are often “vulnerable” in other ways, too. Often, they are vulnerable in the sense of suffering from medical conditions that make them suitable subjects for the experiment. Such people are vulnerable, too, in the sense that existing medical treatments of their condition are less than completely satisfactory (we would not be doing the experiment, certainly not on them anyway, otherwise); and the new trial treatment might be an improvement.

When experimental treatment is expected to have positive therapeutic effects for the experimental subject as well, we are in the happy position of being able to justify the procedure on therapeutic grounds alone, and to treat any experimental payoffs as wholly unintended by-products. Often we are not in this happy state, though: realistically, we know that the benefits will be wholly or principally for other patients who come later, suffering from the same condition, rather than the patient upon whom the experiment is being performed. Still, even in this less happy scenario, we have a case of vulnerability-versus-vulnerability—the vulnerability of the experimental subject, versus the vulnerability of those who stand to benefit from the experiment. In any systematic application of our duty to “protect the vulnerable,” those potential gains to vulnerable agents must be borne in mind, alongside all those other concerns about risks of vulnerable people being ill-used in research.

For a particularly striking example, consider the continuing controversy over the exclusion of elderly people from clinical trials of drugs and medical procedures deployed commonly on the elderly. The issue is nicely set out in 1997 Editorial in the *British Medical Journal*:

Practitioners face a difficult paradox in prescribing for the elderly. Those aged over 65 comprise only about 14% of the population in most industrialised countries, yet they consume nearly a third of all drugs. Ample evidence indicates that, even in healthy elderly people, aging impairs the way the body handles drugs. In ill elderly people these changes can be exaggerated considerably.

In an ideal world data from premarketing and postmarketing surveillance studies would describe how a drug is likely to affect older patients differently from younger ones. Unfortunately, rather than being oversampled in clinical trials, to reflect their distribution in the drug consuming population, elderly people are inadequately represented.²⁴

In some cases, the design of the trial literally excludes people over a certain age, for no scientifically justifiable reason.²⁵ Other times the elderly are not formally excluded but are radically underrepresented in clinical trials. A recent RAND study analyzing patient and trial characteristics for 59,300 patients enrolled in 495 National Cancer Institute trials from 1997 through 2000 found, tellingly, that while 61% of cancer patients were elderly, only 32% of participants in clinical trials were elderly.²⁶

Clearly, this is bad science. Insofar as the elderly are major users of those drugs and procedures, and insofar as the elderly do not react to them in the standard way, physicians clearly

need those clinical trials to give them more information about the reactions of the elderly. And that is the way the issue is typically presented. The AMA's Code of Ethics instruction on "subject selection for clinical trials" says, for example, that "Inclusion and exclusion criteria for a clinical study should be based on sound scientific principles."²⁷

The reasons that the elderly are so often excluded or underrepresented in clinical trials of drugs, even those to be used predominantly by the elderly, are many and varied. The *BMJ* Editorial points to some:

The "old old" are a messy lot physiologically. They are far likelier than the young to have coexisting medical problems, for which they are likely to be taking other potentially interacting drugs. They also have the distressing property of being more likely in the middle of a trial to suffer an infarct of the heart or brain or simply to drop dead. They are bad news for the drug development process.

Yet another reason is that the elderly often count among those who would qualify as "vulnerable" in various respects, from whom we therefore cannot obtain meaningful consent. They are more likely to suffer cognitive impairments associated with the aging, they are more likely to be institutionalized, and so on. In addition to the pragmatic and scientific issues, then, there are also these ethical issues in obtaining meaningful informed consent associated with conducting clinical trials on the elderly. Ethical worries about their vulnerability, too, get in the way of including the elderly in experiments, in ways we scientifically should.

Instead of construing this as an issue of "ethics" versus "good science," however, we can see it as an issue of "ethics versus ethics." Indeed, the ethical considerations on both sides can be seen to be broadly of a cloth, insofar as both involve an attempt to "protect the vulnerable." On the one side, we need to protect vulnerable research subjects from ill-usage in the experimental procedure. On the other side, we need to protect vulnerable patients from being prescribed drugs that have not been adequately tested on populations relevantly similar to their own. Saying that "vulnerabilities are involved on both sides" does not, of course, automatically tell us where exactly the balance should be struck. But the problem of weighing the competing considerations is nonetheless rendered far more tractable by getting them both on the same scale.

Of course, there can be no thought of press-ganging subjects into experiments literally against their will. Kipnis is surely right to say that "the wrong committed by experimenting on an unwilling subject is of far greater seriousness than the wrong committed by unjustifiable exclusion."²⁸ But that is not what is being contemplated, here. What is in view here is a consenting subject, albeit one who is vulnerable in ways that make us worry about the quality of that consent. In deciding on balance whether to go ahead and include the subject in the experiment, those worries notwithstanding, the benefit in prospect to other vulnerable agents ought I suggest be one further consideration weighing in favor of proceeding—particularly where, as perhaps with the elderly, the great majority of other potential experimental subject of the relevant sort would be consenting under similarly compromised conditions.

V. Conclusion

The problem I have been wrestling with is why we should hesitate to experiment or operate on people who are vulnerable in ways compromising their capacity to consent—but why it might be all right to go ahead, despite those hesitations.

My own preferred solution is to introduce "autonomy interests" into a consequentialistic model, which imposes a general duty on all doctors (and all others) to protect the interests of those who are especially vulnerable to their actions and choices.

Other philosophers no doubt would prefer more deontological foundations. To them, I offer this closing observation. If you think the Nuremberg Tribunal got it broadly right, then for an experiment to be permissible it has to be *both* "right" and "good." That is to say, the researcher not only has to have the consent of the experimental subject; she also has to have good grounds for thinking that some good will come of the procedure.

To those taught to see deontology and consequentialism as mutually exclusive alternatives, this requirement that the experiment be "both right and good" constitutes an interestingly different hybrid. It bears pondering how many more situations, other than medical experimentation, might manifest that same structure.

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Endnotes

- * An earlier version was presented to the American Philosophical Association, Pacific Division, Pasadena, March 2004. I am grateful for comments there, particularly from Ken Kipnis and Jeff Blustein.
1. These are the sorts of things catalogued most ably, for the experimental case, in Kipnis 2001; see further Kipnis 2003.
 2. Goodin 1985, ch. 5.
 3. Goodin 1985, 62-70, discussing doctor-patient relations alongside lawyer-client ones as instances of "professional responsibilities" more generally.
 4. Goodin (1985, 62-70) raises doubts about the parallel voluntaristic account of professional responsibilities of doctors toward their patients: there it is argued that the reason doctors have special responsibilities toward their patients is not because of any voluntarily self-assumed obligations but, rather, because patients' vital interests are particularly vulnerable to their doctors' actions and choices. Similar issues are raised as regards researchers and experimental subjects in H. Schuch1994.
 5. An alternative deontological ethic might for example make its prime directive "respect for persons," which is ordinarily manifested by securing their informed consent before undertaking any medical procedures on them, but can also be manifested in various other ways as well. But if we do not necessarily have to secure a person's informed consent to a procedure, vulnerability compromising that person's capacity to give meaningful consent is then not necessarily a problem. To see why vulnerability might be a problem, in deontological terms, we therefore need to focus on versions of deontological ethics that prioritize informed consent.
 6. Because, in Hobbes's (1651, ch. 14) terms, the "sign" does not, in the case of such agents, "sufficiently argue their will."
 7. A hard-line deontological analysis would accommodate the latter case by literally equating the consent of a legally authorized representative with the consent of the person whose agent it is: when the agent consents, the person whose agent it is thereby consents. In the absence of that formal legal authorization, however, there seems to be no way on a hard-line deontological ethic for that transfer of agency to be affected. There is no plausible story that could be told about how, "when the surrogate decision-maker has consented, the person on whose behalf the decision is being made has thereby consented."
 8. Cf. World Health Association 1989, Principle 11.
 9. Nuremburg Tribunal 1949.
 10. Kipnis 2001, 177.
 11. US Code of Federal Regulations 1996.
 12. Kipnis 2004.
 13. World Health Association 1964, Principle 10 (emphasis added). That Principle goes on to say that, "In that case the informed consent should be obtained by a physician who is not engaged in the investigation and who is completely independent of this official relationship"; and the next Principle goes on to say that, "In case of legal incompetence, informed consent should be obtained from the legal guardian in accordance with national legislation. Where physical or mental incapacity makes it impossible to obtain informed consent, or when the subject is a minor, permission from the responsible relative replaces that of the subject in accordance with national legislation."
 14. Thus, for example, under each of the dimensions of "vulnerability" he discusses, Kipnis (2001, 178-9) proposes "measures researchers might take to address" the limitations those vulnerabilities imply for capacity for meaningful consent. In some cases, those measures are designed to make vulnerable people's consent more meaningful (in the case of cognitive vulnerabilities, e.g., with "plain language consent forms" or "supplementary educational measures") and other times involve measures to make sure that vulnerable agents' interests are protected, albeit not through the agency of those agents themselves (in the case of cognitive vulnerability again, through "the proper use of surrogates and advocates").
 15. My favorite version remains Ronald Dworkin's (1974, p. 18): "Suppose you and I are playing poker and we find, in the middle of a hand, that the deck is one card short. You suggest that we throw the hand in, but I refuse because I know I am going to win and I want the money in the pot. You might say that I would certainly have agreed to that procedure had the possibility of the deck being short been raised in advance. But your point is not that I am somehow committed to throwing the hand in by an agreement I never made. Rather you use the device of a hypothetical agreement to make a point that might have been made without that device, which is that the solution recommended is so obviously fair and sensible that only someone with an immediate contrary interest could disagree. Your main argument is that your solution is fair and sensible, and the fact that I would have chosen it myself adds nothing of substance to that argument."
 16. "If I consent to your killing me, you would not thereby be permitted to do so. That some deed is okay with me does not always mean it is okay," as Kipnis (2001, 176) observes. The best story hard-line deontologists can tell here, presumably, is akin to Mill's (1859, ch. 5) argument against slavery contracts: respect for autonomy does not oblige us to respect autonomous choices to extinguish autonomy, whether by selling oneself into bondage or by killing oneself either. That would oblige physicians to engage in the cruel prolongation of a terminal patient's autonomous existence, however painful and ultimately pointless, contrary to the patient's clear and rational preference for a more dignified end of his choosing. Many hard-line deontologists will reply "quite so" to that proposition, of course; but the reference to "dignity" in that case description might give pause to at least some deontologists who see respect for persons as being linked as much to "human dignity" as it is to "moral autonomy."
 17. Especially, perhaps, the worry that other interests can outweigh autonomy interests too easily and often, if autonomy is seen as just one interest among many. Unless we make autonomy interests lexicographically prior to all others, we will be unable to satisfy those who demand that no medical procedures could ever be performed without the consent of a person who is actually capable of granting or withholding consent.
 18. Kipnis 2001, 176.
 19. Nuremburg Tribunal (1949, Directive 9) requires that, "During the course of the experiment the human subject should be at liberty to bring the experiment to an end if he has reached the physical or mental state where continuation of the experiment seems to him to be impossible."
 20. "Forgotten" in the literature of medical ethics, if not the practice of IRBs, where it is standard practice to subject proposals first to a consequential-style risk-benefit calculus and then an informed consent test.

21. Nuremberg Tribunal 1949. See similarly World Health Association (1964), whose Basic Principles 1-8 correspond broadly to the Nuremberg Tribunal (1949) directives above, with Principles 9-12 pertaining to issues of informed consent. Similar conditions to those quoted above are written into the provisions of the *US Code of Federal Regulations*, both pertaining to protection of human subjects in general and to the waived-consent experiments discussed above (US Code of Federal Regulations 2001 and 1996 respectively).
22. Note that I describe these considerations as “consequential” or “consequentialistic in form” —by which I just mean “outcome-oriented.” Why those should matter is, of course, easily analyzed in terms of consequentialistic ethics. But it is of course possible to incorporate them into a deontological ethic as well (as, for example, duties of beneficences are within Kant’s ethics). The task of those preferring to construct a hybrid model from a deontological starting point would be to find some such way of these consequential considerations within that sort of ethic.
23. AMA 2001. World Medical Association 1948.
24. Arvon 1997.
25. Gurwitz, Col and Avorn 1992. Bugeja, Kumar and Banerjee 1997. Bayer and Tadd 2000.
26. Lewis et al. 2003. See similarly Gurwitz, Col and Avorn 1992.
27. AMA 2003, sec. E-2.071.
28. Kipnis 2003.

Vulnerability in Research Subjects

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The concept of “vulnerability” was basically grandfathered into the literature of research ethics, without certification. Though the Nuremberg Code emphasized the necessity of the candidate-subject’s informed consent, it ruled out essential research on children and those with cognitive impairments. In the United States, episodes like Willowbrook, the Brooklyn Jewish Chronic Disease Hospital Case, and the Tuskegee Syphilis Study provoked the debates that eventually gave birth to our current methods for ensuring the ethical conduct of research. But despite the remarkable circumstances of the subjects involved in those three studies—institutionalized children, hospitalized elderly, and impoverished and poorly educated black Alabama males—it is not much of an exaggeration to say that, in the minds of many investigators, the paradigmatic research subject remained a mature, respectable, moderately well-educated, clear-thinking, literate, self-supporting United States citizen in good standing: i.e., a man (sic) who could understand a 12- page consent form and act intelligently on the basis of its contents. Though it is assumed here both that the existing guidelines are sufficient to deal ethically with this paradigmatic research subject and that the default protections are reliably in place, the vulnerable research subject nonetheless required an ethical consideration going beyond that baseline.

The prevailing “subpopulation” approach seeks to modify these baseline standards for groups falling outside of the paradigm. The Federal Regulations on the Protection of Human Subjects (45 CFR 46) implement the requirement that institutional review boards (IRBs) take into account the “special problems of research involving vulnerable populations, such as children, prisoners, pregnant women, mentally disabled persons, or economically or educationally disadvantaged

persons.” Although some of these groups have received their own “subparts” setting out special requirements, it is surely reasonable to have comparable concerns for drug abusers, the desperately ill, Ugandan women, illegal aliens, the impoverished homeless, women in the process of miscarrying, psychology undergraduates, and the elderly in the early stages of dementia. The twin tasks of confirming subpopulation vulnerability and identifying requisite protections have been plagued by conceptual murkiness. What exactly is “vulnerability” as applied to research subjects? And what should be the methods and goals in responding to it? Though commentators speak as if there were something common to these disparate groups, it has not been clear what that characteristic (or that set of characteristics) is. And even if such criteria were articulated, one would surely want to know what it was about those features that made those who possess them “vulnerable.”

I am here challenging the current subpopulation focus that is evident both in the writings on research ethics and in the efforts to draft subparts for groups designated as vulnerable. I am urging that the current conceptualization be supplanted by an “analytical approach,” like the one to be set out here. The aim is to tease out the circumstances that directly signal the specific vulnerabilities researchers should take into account. Seven discrete types of candidate research subject (C-S) vulnerability can be distinguished, each paired with a distinct question and compensating strategies. Foreshadowing, here are the seven.

- Cognitive: Does the C-S have the capacity to deliberate about and decide whether to participate in the study?
- Situational: Does the C-S have the time and composure needed to understand and choose whether to participate in the study?
- Juridic: Is the C-S liable to the authority of others who may have an independent interest in that participation?
- Deferential: Is the C-S given to patterns of deferential behavior that may mask an underlying unwillingness to participate?
- Medical: Has the C-S been selected, in part, because he or she has a serious health-related condition for which there are no satisfactory treatments?
- Allocational: Is the C-S seriously lacking in any important social goods that will be provided as a consequence of his or her participation in research?
- Social: Does the C-S belong to a socially disvalued group?

It is useful to return to the idea of consent, so central to the Nuremberg analysis. As with other performatives, to grant consent is to exercise an ethical power. We have the ability, merely by intoning the proper words under the right circumstances, to alter the systems of obligations and permissions that envelope us. Ordinarily it is a wrong for you to take my lawnmower. But if I say “You can take my lawnmower,” an action that would have been wrong can become unexceptional. In giving permission, an act can become permitted. So the granting of consent by an informed candidate research subject (a C-S) is a precondition for ethical research.

Some types of vulnerability interfere with one’s ability to give or withhold informed consent. Children, the uneducated, and persons with mental disabilities may lack the capacity to

appreciate their situations and deliberate. Still others with unexpected, exigent medical conditions (women having miscarriages, for example) may lack the time and composure needed to become informed, though they are not mentally disabled. These two vulnerabilities—“*cognitive*” and “*situational*”—each represent a limit on the ability to provide informed consent. Several strategies exist to compensate for cognitive vulnerability: plain-language consent forms, advance directives (where incapacity is anticipated), supplementary educational measures, and the proper use of surrogates and subject advocates. Situational vulnerability can be addressed by community consultation and notification procedures in the context of waived consent trials for patients in emergency circumstances.

However, the five other vulnerabilities are different. For even if informed consent is present, it may not suffice to affect the permissibility of research. When consent is given, something that wasn't permitted thereby becomes permissible...usually. So if a doctor asks to examine a patient who now says “OK,” this typically brings it about that the physical examination becomes OK. To consent is—characteristically but not always—to exercise a power to alter ethical relationships. Consent can change the system of obligations, permissions, and prohibitions within which we live.

Though we usually think that to give informed consent is to grant permission, and to grant permission is to bring it about that some formerly prohibited act becomes permitted, informed consent in research is often insufficient to bring about permissibility. The science may be bogus; the people selected for a burdensome trial may be different from those who can benefit from the results; the risks and burdens may be excessive; there may be dangers to third parties; those conducting the study may not be up to the job; the political, organizational, economic, and social settings may not offer the integrity and resources required by the trial; and so on. While non-vulnerable participants can be wrongfully placed in harm's way, subject vulnerability was never intended to pick out all of the areas where researchers and IRBs have to be careful. Vulnerability is only one chapter of the research ethics story.

We can now examine the second route to vulnerability. Consider the following cases (Kipnis, 1992):

Riley#1, unable to swim, finds himself on a raft that is sinking slowly in deep water. Mr. Hathaway, alone on the nearby shore, offers to throw a lifeline and rescue him, but only if Riley#1 agrees to pay him \$10,000. Riley#1 consents and is rescued. Does Riley#1 owe Mr. Hathaway \$10,000?

Riley#2 finds that he has a life-threatening but curable illness. Dr. Hathaway offers to administer treatment that will cure him, but only if Riley#2 agrees to pay him \$10,000. Riley#2 consents and is cured. Does Riley#2 owe Dr. Hathaway \$10,000?

There are at least three ways of thinking about these cases.

Some—notably libertarians—treat the cases identically. Neither “rescuer” is responsible for the other's precarious situation. Neither has a legally cognized duty to intervene. Neither makes anyone worse off. Both have offered assistance—at a price, of course—and a deal is a deal.

A second group sees a powerful argument for lifeguards and universal health coverage. Just as we tax ourselves to support municipal fire fighters, those facing other life emergencies should not have to purchase vital assistance in the marketplace. An economy is ethically flawed if it treats certain vital goods as commodities. Although this approach is

revealing, it dodges our question: Do the Rileys owe their debts even in flawed economies?

Finally, some will scrutinize the terms of the two contracts. While it may not be unjust to have to pay \$10,000 for \$10,000 worth of medical care, that same sum is excessive payment for modest assistance in getting out of the water. Though both Rileys can knowingly and voluntarily enter into their respective agreements, the terms of the first contract appear to be exploitative and unconscionable, the price reflecting the fatal consequence of refusing the offer rather than the minor costs of providing the service.

Both Rileys are vulnerable: precariously situated and at the mercies of their respective Hathaways. Each expects death as the consequence of rejecting the offer. But each is capable of informed consent, appreciating exactly what they must understand, and choosing reasonably enough under the circumstances. Though there is vulnerability in both cases, only Mr. Hathaway—not Dr. Hathaway—is taking unfair advantage of it. I do not think it would be exploitation if Mr. Hathaway had asked Riley#1 to pay—not \$10,000—but only \$10, to clean clothing he would soil in the rescue. Vulnerability makes it disturbingly easy to impose agreements that unjustly allocate benefits and burdens. These transactions must be scrutinized carefully.

This second type of vulnerability does not limit informed consent. Where the candidate-subject is (1) juridically subordinated (like students, employees, soldiers, and inmates); or (2) deferential (like certain children, students, military enlistees, employees, and third-world woman); or (3) seriously lacking in opportunities or material resources (like prisoners and the Tuskegee subjects); or (4) without safe and effective medical options (like many in cancer research); or (5) socially disvalued (like prisoners, children, women, and minority groups), it is possible that the research should not be done even with informed consent, and certainly not until compensating measures are implemented.

Juridic vulnerability calls attention to the formal authority relationships that often characterize social structures. The most striking examples are prisons and the military, where wardens and officers have legal authority over prisoners and enlistees. But the category also includes children under the authority of their parents, psychology students subordinated to their college professors, institutionalized persons (including institutionalized children and their parents) subject to the authority of custodians, and certain third-world woman who may be legally subject to their husbands. Related issues can arise when the candidate-subjects are engaged in illicit activities. This catalogue is not exhaustive.

In these cases researchers must ask: “Is the C-S liable to the authority of others who may have an independent interest in that participation?” The worry is that the “consent” of the C-S might be merely a reflection of the wishes of those in authority. This distinctive vulnerability—the juridic fact of their subordination to the authority of another—can call into question the validity of their consent. This is especially a concern when those in authority are also those who are conducting, commissioning, or somehow benefiting from the research.

In its Final Report on human research in the military, the Advisory Committee on Human Radiation Experiments (ACHRE) recommended that officers be specifically excluded from recruitment sessions and that an ombudsman be present to insure that the voluntariness of participation is adequately stressed. Likewise, children can be questioned separately from their parents and confidentially. The task for the researcher is to devise a consent procedure that will adequately insulate

the C-S from the hierarchical system to which he or she is subject.

While juridic subordination directs our attention to objective features of the formal hierarchical context within which the C-S functions, **deferential vulnerabilities** are, instead, subjective responses to certain others. To be sure, the two are often present together. With respect to officers, enlistees are generally both deferential and juridically subordinated. But when, in the presence of intimates and friends, one is exhorted to stand up on behalf of a popular cause, one may care deeply about the opinions of those others even though they do not occupy formal positions of authority. Researchers need to understand these powerful social and cultural pressures and devise consent procedures that take them into account. Those involved in subject accrual need to be selected with care, perhaps with the advice of local informants or consultants in psychology and anthropology. The conversational setting may require attention. The challenge is to devise a process that eliminates as much as possible the social pressures that a candidate-subject may feel even if, in reality, they are not being imposed.

Medically vulnerable candidate-subjects are those who are under consideration because of serious health-related conditions for which there are no satisfactory remedies. Metastatic cancers can fall into this category, as can severe spinal cord injuries, Parkinson's disease, multiple sclerosis, Alzheimer's disease, end-stage AIDS, and so on. Also included are illnesses for which there are treatments that are not suitable for particular patients. Rescue therapy for cancer, requiring transfusions, is not a suitable treatment for most Jehovah's Witnesses.

What makes these patients vulnerable is their medically exigent state. Having run out of options, they will be willing—even eager—to undergo risks that would ordinarily be foolish. The classic problem with research on medically vulnerable patients is an apparently ineliminable “therapeutic misconception” affecting the majority of these subjects. The patients know there are no satisfactory standard treatments and that, based on pre-clinical research, scientists are testing a drug that might be safe and effective. Despite warnings to the contrary, many of these subjects are eager to enter trials on the chance they will benefit from access to a drug that works. But Phase 1 clinical trials are not supposed to be about efficacy: They are primarily designed to assess safety. The research subject is vulnerable—so the story goes—because he or she is driven by a false but persistent hope for a cure and, accordingly, is likely to enter the study out of an unreasonable expectation of success. But even if the unproven drug is, in reality, both safe and effective, it is often unlikely that a medically exigent research subject can benefit from it. Since the primary purpose is to assess safety, patients may receive theoretically sub-therapeutic dosages. But instead of receiving increased dosages when tumors progress without adverse reactions, patients are typically removed from the study and denied possible benefits. And even if efficacy appears, the trial can end, leaving improving patients in the lurch.

A fairer division of benefits and burdens would require that trials be designed to assure patients that they WILL have a chance of benefitting from participation IF it turns out that the drug is safe and effective. To fail to do so is to take unfair advantage of these research subjects' vulnerability. One way to do this would be to guarantee to subjects that there are only five ways in which they will come off the study. Either (#1) they choose to leave the study; or (#2) they seriously fail to comply with the protocol and are removed; or (#3) significant adverse reactions are seen in response to the drug

and the trial ends; or (#4) they die; or (#5) they are stabilized or cured. While candidate-subjects should be assured that #5 is unlikely, the study design takes seriously the medically exigent patient's overriding interest in maximizing the possibility of therapeutic benefit. It is a less exploitative arrangement. Under this “maximum therapeutic benefit” standard, the primary concern would still be the scientific validity of the research design. But, having satisfied that requirement, the patient's powerful interest in improvement would have to appear prominently on the researcher's radar screen.

If the internal benefit of research is a safe and effective therapy, the external benefits are the various other compensations that research subjects receive. But a C-S in a state of **allocational vulnerability** is seriously lacking in other socially distributed goods: money, housing, medical care, childcare, burial benefits, opportunities to benefit the community, and so on. The question for the investigator is: “Is the C-S seriously lacking in important social goods that will be provided as a consequence of his or her participation in research?” (On occasion, it may also be pertinent to ask whether the C-S is seriously burdened with social evils that will be relieved as a consequence of participation. This issue is especially pertinent for research on prisoners.)

Now if Job-Seeker is destitute and hungry, and Business-Owner offers him a good job at a decent wage, and Job-Seeker accepts (notwithstanding that it is the only acceptable option), we would not concern ourselves with the voluntariness of the acceptance so long as the terms of employment were fair. But if Business-Owner offers sub-subsistence compensation, and the work is dangerous, and there are no workers' compensation benefits, communities are likely to invalidate the agreement. We will do this, not because Job-Seeker had no other choice, but because the bargain was unconscionably exploitative. As with medical exigency, the vulnerability is to be found in Job-Seeker's precarious position: economic in this instance. But this allocational disadvantage should direct our attention to the substance of the bargain: Is it fair to the party in the weaker position? The minimum wage, job safety regulations, and workers' compensation benefits are all broadly-supported means of reducing such exploitation.

In biomedical research, the vulnerabilities associated with allocational disadvantage arise in many ways. The researcher needs to ask whether the deprivation has led to acceptance of an exploitative offer. While allocations are often the result of impersonal socio-economic forces, the basis for ethical concern is compounded when someone with juridic authority over the C-S is distributing the goods in question. Prisons and the military, for example, may function in this way. It is difficult to distinguish between just and unjust compensation packages. Of the seven types of vulnerability, allocational disadvantage is probably the most problematic. We often assume that if a bargain is satisfactory to both parties, others should not interfere. But participation as a subject in medical research can impose risks and burdens that properly attract community attention. While we do not want to see people treated unfairly, we are not very confident applying the concept of the just price.

I suggest we consider the standards that we routinely apply to other comparable remunerative activities. Although the point has been urged before, it is hard to grasp why research subjects should not normally be entitled to medical treatment for the injuries they suffer; why they should be asked to subsidize the research enterprise in that unusually burdensome way. Surely if we extended broad community standards into this aspect of research, we would begin by securing a right to some version of “workers' compensation.”

Social vulnerability points to the ways in which entrenched prejudice and stereotypical thinking can compromise the care and consideration that would ordinarily be present. The question for researchers is “Does the C-S belong to a socially undervalued group?” The worry is that stigmatizing perceptions will adversely affect the process of developing, implementing, and reviewing the protocol. Although more needs to be said about the appropriate responses to this type of vulnerability, the involvement of members of these socially disvalued groups in the review and implementation process could provide some needed protection, along with corrective education as needed. Projects that needlessly single out the members of such groups for study might well require added scrutiny during the review process.

Finally, the sensitive understanding of vulnerability—the many precariousnesses that afflict the human condition—exposes a certain universality in these themes even while grounding a broader case for kindness and sensitivity. None of us is without some cognitive limitation. Everyone is subject to juridic authority, not all of which is wisely benevolent. Socialization itself entails patterns of deference. All of us face an eventual and too real prospect of medical exigency. And no one is immune from extreme and exigent need and the harms that can flow from prejudice and other deficits in the systems we count on to provide us with essential services and protections. Nor are researchers the only ones who need to learn how to engage the vulnerable with sensitivity and honor. The topic surely has an importance extending beyond the boundaries of research ethics.

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Reflections on Kipnis’s Concept of Medical Vulnerability

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Kipnis makes several significant contributions to understanding and responding to various types of vulnerability in research participants. Most importantly, he replaces the federal regulations’ “subpopulation” approach to identifying and responding to vulnerability with an “analytic” approach. Distinguishing seven types of participant vulnerability, namely, cognitive, situational, juridic, deferential, medical, allocational, and social vulnerability, he recommends a special protection for each (Kipnis 2001; Kipnis 2004a). His analysis of medical vulnerability and its remedy is provocative and problematic.

We consider the adequacy of Kipnis’s assessment of the source and scope of medical vulnerability and his recommended special protection for medically vulnerable participants. Moreover, we weigh whether his proposal to maximize therapeutic benefit is more appropriately incorporated in modified regulations for the protection of vulnerable research participants or is best viewed as an aspirational guideline for researchers and IRBs.

Background

Human research participants routinely are assured several core protections. For example, IRBs engage in prior interdisciplinary review of the study protocol, the consent process and consent form, and they assess whether the risks that have been minimized are consistent with sound research design and whether the risks are reasonable in light of the benefits.

Researchers and IRBs often go beyond the core protections and provide one or more special protections as well. More rigorous recruitment and consent procedures are two of the most common types of special protections (see examples in list below). Without being exhaustive, the following list shows the range of special protections that can be used to mitigate vulnerability.

- Assign recruitment responsibilities to someone independent of the study
- Support the consent process with additional educational activities, use consent advocates or surrogates, strengthen disclaimers in the consent process and materials, formally assess competence and comprehension
- Require additional levels, frequency, and types of review of the study and its conduct
- Increase representation by those who are to participate in the research in the design and/or review of the study
- Minimize risk through the conduct of more preclinical studies, use of clear stopping rules and data safety monitoring boards (DSMBs), and compensation of participants in the event they are harmed
- Increase benefits by insisting on the prospect of therapeutic benefit, and direct adequate attention to the merits of the study question and design
- Cap the level of risk for research involving children, per regulation

Depending on the study design, the vulnerability of the participants, and the investigational interventions, among other factors, any number of these special protections may be appropriate.

Kipnis on Special Protection for Medically Vulnerable Participants

Prospective research participants are medically vulnerable, Kipnis maintains, when they have serious health-related conditions for which there are no satisfactory treatments, putting them at increased risk of being exploited for research purposes. What makes them vulnerable is “having run out of options, they will be willing—even eager—to undergo risks that would ordinarily be foolish.” An “ineliminable ‘therapeutic misconception’” drives their “false but persistent hope for a cure,” and they are “likely to enter (studies) out of an unreasonable expectation of success” (Kipnis 2001, 2004a).

Kipnis maintains that participants need to be protected from researchers’ inattention to medical vulnerability and “agreements that unjustly allocate benefits and burdens” (Kipnis 2004a). He urges researchers and IRBs to be more responsive to participants’ “overriding interest” in a chance at therapy. Particularly provocative is Kipnis’s suggestion that IRBs and researchers attend to the arrangement of benefits and burdens between a researcher and her study participants—“to the substance of the bargain.” This introduces a set of considerations different from those that IRBs customarily attend to. In Kipnis’ view, researchers and IRBs should be more vigilant and purposeful in their efforts to protect prospective participants from exploitation. It is the unfair taking advantage

of participants deprived of therapeutic options that Kipnis believes needs to be remedied.

Special recruitment and consent protections are insufficient in Kipnis's view. The risk of the therapeutic misconception by medically vulnerable participants is so high, serious, and inevitable, that it is futile to expend effort to mitigate it. He advocates, instead, a sole special protection for medically vulnerable participants—namely, maximizing therapeutic benefit—not only within a study, but possibly long-term after the completion of a study. He asks, “given the interests and aspirations of both parties (and the poor bargaining position of one), is there a fair division of the benefits and burdens of cooperation?” (Kipnis 2001) His objective is to make the cooperative relationship between researcher and participant as well as the arrangement of benefits and burdens between them, fairer, kinder, and more sensitive. (Kipnis 2001, 2004a).

Critique

Kipnis's proposal exceeds the bounds of common IRB practices and the regulatory requirements that the risks of a study be minimized and be reasonable in light of any expected benefits. But how should we understand his recommendations? Is he, for instance, offering a new regulatory standard for protecting medically vulnerable participants?

We believe Kipnis's recommendation is best understood as aspirational, rather than a minimum requirement of the sort that comprise regulations. He acknowledges that promising therapeutic benefit after the completion of a study does not transform a study in which the risks are unreasonable, into a study in which they are reasonable (Kipnis 2004b). But it can enhance the fairness of the relationship between researcher and participant. It has the potential to make the “arrangement” of interests fairer and less prone to exploitation. Considering and adjusting the arrangement of interests between the researcher and study participants is an activity different from adjusting the arrangement of risks and benefits within a study. Kipnis' recommendation to maximize therapeutic benefit is more a type of inducement or compensation than a protection.

It is well recognized that efforts to sweeten invitations to clinical research raise the prospect of unduly inducing people to participate. Kipnis does nothing to reassure us that his open-ended call for maximizing therapeutic benefit avoids problems of undue inducement and protects against the therapeutic misconception and exploitation. Requiring or even allowing offers of therapeutic benefit at the end of a study, depending on the study, may be counterproductive (Dresser 2002). When there is little prospect that a therapeutic benefit will become available after a study, promises of possible future benefit may encourage medically vulnerable persons to agree to participate in studies they would not otherwise agree to. Such promises can easily exacerbate rather than mitigate the therapeutic misconception. If the prospective participant inferred “I might get better” when told “You will undergo these risks, but therapeutic benefit is unlikely and not to be expected,” surely she will infer, “I will benefit” when promised; “If there is benefit later, you will receive it.”

Recommending that investigators promise participants a potentially therapeutic study intervention either within studies or after the studies have been completed, is reasonable in some cases (Freeman 1999). Kipnis's error lies in generalizing from his reflections on one particular study (a phase I dose escalation study of an angiogenesis inhibitor—which boasts an unusually low toxicity—in cancer patients lacking other options) to all studies involving medically vulnerable participants (Kipnis 2001, 2004a). Kipnis himself lists a wide

range of circumstances in which people may be medically vulnerable: metastatic cancer, severe spinal cord injuries, Parkinson's disease, multiple sclerosis, Alzheimer's disease, end-stage AIDS, and rescue transfusions for Jehovah's Witnesses. His examples of an angiogenesis inhibitor in cancer patients and transfusions in Jehovah's Witnesses provide important clues that issues of vulnerability and special protection involve attention to multiple considerations, including characteristics of the particular disease, the particular intervention(s) being studied, and the study design. The diversity of medically vulnerable people and types of studies involving them suggest the implausibility of just a single special protection for this category of vulnerability.

Moreover, we disagree that efforts to mitigate the therapeutic misconception are futile. Instead we join Appelbaum and Dresser, among others, who maintain that there are ways to avoid and minimize the force of the therapeutic misconception (Appelbaum 1987; Dresser 2002). In our view, therefore, Kipnis is unwise to reject and abandon special protections directed at recruitment and consent for medically vulnerable participants. It is important to embrace these and many other special protections depending on the particulars of a given study.

Kipnis's proposal to maximize benefits is problematic for practical reasons as well. It is so stringent a standard that it makes many otherwise acceptable studies infeasible; it needs qualification. Requiring that the therapeutic benefits be maximized—without further qualification—may have the unintended effect of raising the bar on what research can and will be conducted. It may make the conduct of some research prohibitively expensive and so burdensome for sponsors, researchers, and funders that it will not be conducted. From where shall researchers find the funds to cover the costs of long-term continued use of investigational interventions after a study is complete? Might the obligations differ depending on whether the researcher is an individual clinician or a manufacturer? What sorts of competing interests of the researcher, in Kipnis's view, might be compelling enough to limit the obligation to maximize therapeutic benefit for participants in her studies? Moreover, researchers may not be permitted to promise an unapproved FDA-regulated product off-study without prior approval from the FDA—an approval that may be difficult to obtain so far in advance. Alternatively, if Kipnis is calling for radical changes in the institutions and infrastructures surrounding and supporting clinical research, he needs to offer more detail and justification for such radical recommendations.

Finally, unqualified calls for maximizing therapeutic benefit in clinical research, taken to their logical extreme, threaten to dissolve research into therapy and undermine the research enterprise as a whole. This encourages rather than discourages widespread dissemination of unproven interventions, avoidable harms to patients, and unwarranted expenditures. We are not as sanguine as Kipnis about making research resemble therapy as closely as possible.

It must be explicitly acknowledged that medical exigency can justify a departure from the norm separating research and therapy. The conjoining of these two different purposes is justified when 1) illness is severe and 2) no safe, effective, and otherwise satisfactory treatments are available (Kipnis 2001).

The story of surgical research illustrates the drawbacks of conjoining research and therapy. Surgical research traditionally has been exempt from meeting the same scientific and ethical standards as other types of clinical research. This carve-out

allows surgical researchers to focus on delivering therapeutic benefit and to direct less attention to issues of study design and participant protection. Surgical studies on the whole undergo less review by peers, IRBs, funding agencies, and DSMBs. Until recently these practices have received little challenge. For a variety of reasons, however, professional surgical organizations and surgical researchers are now calling for more rigorous surgical trials (Prehn 2004). There is even growing support for the use of placebo controlled surgical trials (Freeman 1999; Miller 2004; Moseley 2002; Vawter 2003, 2004). Although some people worry that participants in such trials are especially vulnerable and in need of special protection, we remain concerned for the participants in surgical activities that prematurely resemble therapy more than research. Participants in placebo-controlled surgical trials may often be better protected, not less. Placebo-controlled trials are more likely to have received independent peer review, be well-designed, have clear stopping rules, be closely monitored, be adequately funded, and to have been reviewed and approved in advance by more than one IRB. All this suggests that rigorously designed surgical trials with reasonable risk/benefit profiles are more likely to have appropriate special protections in place for their participants, than research activities that seek to maximize therapeutic benefit and resemble therapy.

We remain unpersuaded that the core issue concerning medical vulnerability is to develop fairer, kinder, and more sensitive relationships between researchers and participants. The value of familiarity with medical vulnerability is to facilitate selecting the appropriate set of protections (routine and special). When potential participants are vulnerable, researchers and IRBs should consider whether and how the vulnerabilities alter the reasonableness of the study's risks and benefits. The kind of attention that should be directed to benefits is increasing (not maximizing) the full range of potential benefits (not only direct therapeutic benefits) consistent with sound research design, as necessary to render the risks reasonable, consistent with the study's feasibility, and to incent and compensate participants as appropriate.

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Presidents and their Right to Privacy

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Barron H. Lerner, a physician and medical historian, faults the family of Ronald Reagan for keeping healthcare decisions by and about the former President from public scrutiny. He says their decision not to go public with the details of the late president's final years "deprived Americans of the opportunity to learn how the family confronted questions crucially relevant to Alzheimer's patients and their families."¹ The public did not get to know, for example, whether Mr. Reagan executed an advance directive, why the family went ahead with a hip replacement in a demented man of advanced years, or whether there was, at the very end, a decision to forgo treatment. Lerner says that "frank acknowledgement of the difficult choices the family faced could open a broader public discussion about the value, and quality of life, for Alzheimer's patients during 'the long goodbye.'"

The health of presidents always attracts public attention, if only because some presidents and candidates have actively concealed or misrepresented details of their health. In 1972, George McGovern's first vice presidential candidate, Thomas Eagleton, disappeared from the Democratic ticket when the public reacted unfavorably to the not-initially-revealed disclosure that he had received electroshock treatment for depression.² Since that time there has been increased scrutiny of candidates' health, and their medical records, sometimes to little avail. Paul Tsongas apparently fudged the full extent of his cancer while campaigning for the presidency.³

Perhaps the most notorious concealment of ill health involved the disability and extended convalescence of Woodrow Wilson.⁴ John F. Kennedy concealed a variety of ailments that seriously affected his health and required constant medication.⁵ Lyndon Johnson had health problems that played a significant role in his decision not to run for a second term, though he did not say as much in public.⁶ Sometimes circumstances have brought presidential ailments into plain view. Jimmy Carter was hospitalized for hemorrhoids, which by his own admission interfered with key diplomatic initiatives.⁷ Ronald Reagan was hospitalized, of course, following an assassination attempt.

The disclosure of healthcare records prior to election or even while in the White House has at least one very strong rationale to recommend it: the identification of disorders could interfere with job performance, especially weighty and time-sensitive military decisions. Of course, disclosure of records to run for political office remains a voluntary decision. There is nothing in the Constitution that requires a health report in order to serve in political office. People who do not wish to disclose their medical records to run for the Senate, the House of Representatives, or the White House do not have to do so. They risk, of course, voters becoming suspicious that they might be concealing something, but in the end that decision is still theirs to make.

The information Lerner is looking for far exceeds the standards of disclosure that are expected in political life today. Lerner is not suggesting that there may have been evidence of deteriorated mental status while Reagan held office, though some have made exactly that hard-to-substantiate allegation.⁸

If it were true that any president's mental faculties were slipping away in the White House, the public would certainly have a *prima facie* right to know. As far as the Constitution is concerned, a sitting President forfeits the expectation of privacy in regard to any medical condition that would trigger the application of the 25th amendment which provides a mechanism for succession should the President be unable to discharge the powers and duties of the office.⁹ To comply with that provision, both Ronald Reagan and George W. Bush transferred temporary presidential authority to their vice presidents, while undergoing medical procedures.¹⁰ By contrast, Lerner wants the details of President Reagan's decline and healthcare well *after* the man left office. This interest in presidential health healthcare out of office is something new, and bioethics ought to pay attention.

In medical ethics, there is a strong presumption of privacy unless patients waive their rights to it or there are compelling reasons that justify disclosure of certain information to specific parties. The exact reasons for breaching confidentiality are a matter of debate, of course. In the 1980s, the HIV epidemic added new wrinkles to the questions physicians faced in warning third parties about dangers from the psychiatric disorders and communicable diseases of their patients. Not all the public's interest in medical records involves danger to others, however, and attempts to breach medical confidentiality are more dubious than others. For example, in 2003, the U.S. Attorney General unsuccessfully subpoenaed medical records from hospitals in an attempt to determine the scope of a certain kind of abortion procedure.¹¹ Medical confidentiality exists in order to protect people from unwanted scrutiny regarding their diagnoses and treatment, and that should be true for politicians or anyone else who is famous by the standards of the day. Former presidential families do not owe the public the details of former presidents' diseases and deaths unless they choose otherwise. There is no specifically identifiable person who will suffer if this disclosure is not made.

It is almost certain that President Reagan or his family was offered the opportunity to obtain information about advance directives. The federal Patient Self-Determination Act (PSDA) of 1991 requires that healthcare institutions make exactly that offer, and former presidents would be no exception as they enter healthcare institutions. As is well known, the PSDA has made some progress in extending advance directives across patient populations, but its influence is not widespread. Like many other Americans, the Reagans might simply have forgone the opportunity to put instructions in place that would guide later medical decisions. Even if they did, advance directives are not panaceas because unanticipated medical states can occur, leaving an advance directive confusing if not altogether irrelevant. Some advance directives, for example, stipulate acceptable and unacceptable medical treatments, which guidance may or may not apply to a patient's actual condition. For this reason, knowing the details of President Reagan's advance directive (if any) might not tell an especially useful story.

Even without disclosing the details of the former president's healthcare, the Reagan family *has* made considerable contributions to the awareness of Alzheimer disease. In 1994, President Reagan addressed his illness in a public letter in which he said, among other things: "I now begin the journey that will lead me into the sunset of my life." No other president has ever written a public valedictory letter in which he confronted the illness that would destroy him, and he specifically said he wrote the letter to promote awareness of the disease.¹² And, in helping push for federal funding of stem cell research, former first lady Nancy Reagan might well help provide the political impetus necessary to change the

2001 decision of the Bush administration that puts tight restrictions on federal funding of stem cell research. That research might open doors to new Alzheimer treatments.¹³

Yet Lerner thinks that's not enough. He says the Reagans might have helped with a "broader public discussion about the value, and quality of life, for Alzheimer's patients." By all accounts, President Reagan's illness was profoundly disabling.¹⁴ How would the details of the decline help the public at large estimate—as Lerner puts it—the value of life for Alzheimer patients? And what, precisely, does that mean: to estimate the value of life for people with Alzheimer disease? How to make treatment decisions? If that's the goal, the details of Reagan's decline might not be especially helpful. Decisions about the healthcare of people with Alzheimer disease are highly personal decisions, and there should be no lazy assumption that the resources available to the Reagans would be available to all families of Alzheimer patients. Celebrities only go so far as role models.

Information about advance directives and chronic, long-term care is too important for Alzheimer patients, or for any patients with chronic, debilitating illness, to leave to the Reagan family. The healthcare system as a whole has a responsibility to shoulder the main freight of equipping patients and their families to deal with these matters. We should respect the privacy of presidential families because it is important to respect the privacy of all families. We can only be "deprived" of something if we have a reasonable right to it. We have no such right to the healthcare decisions of politicians, actors, or anyone else in the public eye. If some famous families want to come forward with the details of various disorders, that's fine, but it is a decision that should rest with them, as the A.M.A. reminds physicians through its *Code of Ethics*.¹⁵ No one should carp when people exercise the hard-won right of medical confidentiality that allows them a sanctuary to make decisions in keeping with their values and sense of dignity.

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Race/Ethnicity, Health Disparities, and Bioethics

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This work-in-progress mainly addresses how bioethics should respond to health disparities and related issues of racism and ethnic bias. I argue that bioethics should evolve from a self-understanding as primarily a field of ethical analysis (understanding) to one that also includes change-agency (action). I explain that as a white-dominated field, for bioethics to adequately address issues of race/ethnicity, most bioethicists must face their whiteness.

These words are a modification of remarks I was invited to make in response to papers that were presented during the panel on Race and Health at the annual meeting of the Association for Professional and Practical Ethics, 2004, Cincinnati, Ohio: Annette Dula's "As the Disparities Grow Worse..." and Segun Gbadegesin's "Beyond Race or Culture: Toward a Global Bioethics for Equity in Health Care." In different ways, Dula and Gbadegesin provoke bioethicists to consider whether we have the individual and collective will to make a difference about unjust and/or unwise policies and practices that perpetuate inferior health of disadvantaged racial and ethnic minorities.

I agree with Dula that we should be very concerned about backlashes to, and suppressive actions against, reports of health and healthcare disparities. Dula's implied question is whether bioethicists ethically can remain silent when public agencies distort the truth about issues of bioethical importance like health disparities. Also, I agree with Gbadegesin that race is a social construct and that we must address ethical issues in health surrounding socially-designated race and ethnicity to ameliorate and eliminate inequities in the health arena. Furthermore, I agree with Gbadegesin's statements here and Dula's elsewhere that bioethicists should express themselves through social action.

Annette Dula, Segun Gbadegesin, and I agree on many issues regarding race, health, and bioethics. We agree that much needs to be done about racial/ethnic health disparities. However, Dula and I noted in "Wake-up Call: Health Care and Racism" in response to the Institute of Medicine report on healthcare disparities, that:

- "Mainstream health care institutions and professionals have seldom led social reform."
- "Many whites mistakenly believe that racial prejudice no longer exists, that ethnic stereotypes have little negative effect, and that racist practices by individuals and professionals cause little harm."
- "White individuals and white-dominated institutions may deny that they are racist or have racist practices because they fear negative publicity and legal reprisal."

- "A strong response [to healthcare disparities] takes moral courage—a rare commodity."^{1,2}

These comments are as relevant to bioethicists as they are to healthcare institutions and providers.

Ethical issues related to health and healthcare disparities vary in their complexity. In one sense, the ethics of health and healthcare disparities are clear. These impairments in minority health violate ethical principles such as fairness, care, beneficence, do-no-harm, and respect for persons. Bioethicists can do important work in further analyzing the moral issues of health disparities, including examination of structures, policies, and practices.

However, there is a large set of other ethical issues that relate to action. What should be done and how? "Should" relates to what is possible, effective, efficient, and ethical. "How" relates to strategies.³ Dula and I wrote in the *Hastings Center Report* that "seriously addressing biased attitudes and actions requires that institutions divert limited energy, costly time, and precious resources from other important programs." How much energy and time should institutions and practitioners devote to eliminating health disparities? How should such decisions be made? And *what role should bioethicists play?* How much of our time should be spent on eliminating such inequities. Is working on injustice optional?

As a white guy at a historically Black institution (Tuskegee University) and at a Bioethics Center whose primary goal is to address inequities, disadvantages, and other bioethical issues involving underserved minorities, disadvantaged communities, and vulnerable populations, it is clear to me that bioethics should include understanding and action. Understanding includes analyzing bioethics issues and writing and talking about how these issues should be addressed to affect needed changes. Given a principle of moral humility about limitations of our perspectives, such understanding in significant part should evolve through collaborative inquiry that involves diverse individuals, including race/ethnicity, culture, gender, sexual orientation, and locale. As I suggested earlier, one form of bioethical backlash can be much greater analytical attention to health disparities. What is done with such analyses is, however, very important. The usual format is presentation at academic meetings and in peer-reviewed publications. Of course, such publications and presentations are a form of action. This is action in a very passive sense.

If analysis involves speaking and writing in venues that are more likely to evoke changes in policies, structures, and practices, then "action" is more active. We might call this "activist action." Activist action would be an important and needed step for bioethicists to take.

Professor Gbadegesin stated that "bioethics cannot afford to stop at scholarly analysis." Yet, bioethics has always stopped with analysis regarding racial and ethnic inequities. White bioethicists do not suffer these injustices. Our personal freedom and privilege do not suffer if the inequities continue. Prof. Gbadegesin seems to have something else in mind. That is, to retain its heart and soul—its integrity—bioethics cannot stand by while these injustices persist.

Bioethics has addressed many problems internal to institutional settings. While valuable work, this focus recalls the old joke about the child who searches for his lost nickel under the streetlight because that's where the light is. However, he lost his nickel down the street. In bioethics we've targeted patient, patient-professional, and researcher-participant issues, but we've largely ignored structural and policy issues that foster and sustain inequalities and inequities. We have done little to change those structures and policies.

Of course, some bioethicists have provided valuable structural and policy analyses, but this work is very preliminary. For the most part, such commentators have addressed broad issues of social justice. Racism and ethnic bias have not been prominent in such accounts. Most such commentators are white.

What will it take for us to address bioethics issues in racial and ethnic health disparities seriously and adequately through understanding and action? We must *face* racism and ethnic bias, prejudice, and stereotypes in ourselves and in our white-dominated institutions. As white bioethicists, we must face the possibility of our own racial and ethnic ignorance, insensitivity, unearned privilege, prejudice, bias, stereotypes, and moral cowardice if we are to make progress in understanding and acting to make a difference about health and healthcare disparities.

Facing—accepting—believing—that our white racial identities may include many attitudes and ways of thinking and acting that we abhor, is an important step in the personal journeys that we white bioethicists must take if we are to act successfully to address the many inequities that racial and ethnic minorities experience. Such journeys are often difficult, painful, embarrassing, frightening, and humiliating. However, these journeys can also be exhilarating, rewarding, and empowering.

For bioethicists to enact and facilitate social change regarding race, ethnicity, and health, we must find constructive ways to discuss racism, ethnic bias, power imbalances, distrust, and lack of trustworthiness with each other and diverse others. Bioethicists need to become “race talkers” and “ethnicity speakers” in their journeys to affect social change.

In 2002 at the annual meeting of the Association for Practical and Professional Ethics, I was arguing that white bioethicists must face our whiteness in addressing inequities related to race and ethnicity. A black participant observed that I was speaking as a white guy in transition. He remarked that what we really need is change, not self-indulgence.

If in facing our whiteness, including racial and ethnic biases, we mainly target our needs for intrapersonal transitions and growth, then we are merely self-indulgent. However, my focus on personal journeys and growth about whiteness is something else. If white bioethicists are to eliminate injustices in health related to race and ethnicity, we need to address who we are and how we have grown up in America. It is typical of white racial identity for whites to fail to understand themselves as embedded in the flow of racist and “ethnistic” atrocities that our genetic or cultural forebears perpetrated and perpetrate. We generally consider ourselves outside of this historical river. White privilege only reinforces this position. We don’t consider ourselves injured by all this—though we are. However, if we face what it means to be white or member of a disadvantaged minority, and if we really care about eliminating injustice, then our inaction challenges our integrity. Hopefully, motivation ensues.

We can work effectively with people of other racial and ethnic designations if we do not understand and eliminate the biases, stereotypes, negative attitudes and behaviors that beset us? Do we actually think that—as Annette Dula might say—Black folks (and other minorities) don’t get it that we are clueless not only about our prejudices, biases, and related ways of acting, but also about what it is to be Black or Asian or... (you name it) in this country? Of course Black folks and other minorities get it. For example, these “others” get it that white bioethicists—often avoid touching “other sorts of people,” looking them in the eye, or appreciating our unearned privileges.

Bioethicists should include action for change as part of our activities. However, to become effective change agents regarding racial and ethnic inequities, bioethicists must address many negative aspects of our white racial identities. This is a necessary but insufficient step in making changes. Analogous changes must occur in institutional, agency, and governmental practices.

Dr. Gbadegesin argued that bioethicists should become social change agents. In supporting his view, I offer three reasons. First, structural problems that limit access to care and practices that lead to biased and unequal healthcare, not to mention health losses due to inequitable disadvantages in social determinants of health, have far greater adverse effects on our people—*African Americans and other minorities who are our people*—than ethical lapses involving those who generally get fair treatment in the healthcare system. Second, bioethicists have special training, education, knowledge, and relationships that can help us to become effective social change agents. Third, bioethics as a field is strikingly hypocritical if we collectively espouse the right thing and do little to achieve it.

I am not saying that every bioethicist must be a social change agent in the direct sense. Social change takes analysis, strategy development, and action. However, part of our work should aim ultimately at needed change. If almost all of us are just doing analysis, this is wrong.

Ordinary people on the street often assume that bioethicists try to insure ethical practices and policies. We might think that they simply misunderstand. We have taken our job to be analysis—a necessary step toward needed action. Analysis is often intellectually daunting, but it is safe. As the work of Drs. Dula and Gbadegesin show the lost nickel is over there in the unsafe *dark*.

To eliminate racial/ethnic health disparities and improve minority health, such efforts must involve the communities and populations that experience those disparities. These communities and populations should have a strong voice in how to address disparities and in evaluating actions to ameliorate disparities. Some reasons for greater inclusion of community members are epistemological and ethical. If we grant that researchers, community outreach personnel, health professionals, and bioethicists do not and cannot encompass the perspectives and interests of community members, much less what is “good for them,” then a concept of epistemological humility drives inclusion of community members. Interestingly, some epistemological reasons are also ethical. For example, my African American colleagues often point me to an issue of ethical significance that I have missed because I lack their perspective. Also, as I argued at some length elsewhere, fairness and other ethical considerations mandate major community representation and voice in deciding how to address health disparities.⁴ Such work with communities includes public health measures, direct healthcare services, and biomedical and public health research.

Many ethical issues arise in work with communities to address inequities. For example, what is fair involvement of communities and when? Who should have a voice, and how should they be selected? How are fair processes insured? These issues need analysis, strategy, and action.

Bioethicists have done little work in the area of community involvement. Community involvement is essential in social action to make needed changes—essential morally and practically. However, to understand ethical issues in community work, bioethicists must look beyond their institutions. Bioethicists must learn about community outreach, partnering, collaboration, and community-institutional decision making. Simultaneously, bioethicists should turn the spotlight back on

their institutions to address how institutions treat minority communities. When we take these steps, we will be venturing into the dark.

Endnotes

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A Call for Gender: Equity in Medical Tort Reform

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This paper will consider ethical issues arising from medical tort litigation. I will argue that deep changes are required to ensure fairness in litigation and in order to hold morally responsible those corporations that take unnecessary risks with consumers' lives. Such changes are urgently called for given President George Bush's recent petition for a \$250,000 limit on pain and suffering awards in medical tort cases. Bush proposes to limit damages in cases of medical liability to, as he phrases it, eliminate "junk and frivolous lawsuits."¹ The proposed limit is meant to curtail the rising cost of malpractice insurance for medical practitioners, the increasingly defensive practice of medicine (where physicians order unnecessary tests and referrals for their patients to protect against malpractice suits), and the sharp rise in health care costs. By limiting damage awards for pain and suffering in medical tort cases, he reasons, savings of between \$60-108 billion per year can be achieved (2004).²

Bush's proposal overexaggerates the cost to the health care system of medical tort litigation. He fails to address the staggering health care costs associated with a for-profit medical system, where the insurance industry, at great cost to the public, generates billions of dollars a year in profits.³ Not only will Bush's proposed cap be ineffective in reducing costs to the health care system: it may also increase the likelihood of wrongdoing at the corporate level, since corporations that manufacture medical devices/products may find it even more profitable to rush untested products to the market. Most important, for our purposes, Bush is calling for changes that may exacerbate gender inequalities already present in the current system of tort law. The cap he proposes may worsen gender inequalities if it is applied without other radical changes to the structure of medical tort litigation.

In considering gender inequalities, I will take as my starting point the silicone breast implant debate, which is an example *par excellence* of gender issues in tort law. While my paper specifically treats this debate, I herein pursue the broader question of how to best assess the risks to women caused by a wide range of medical technologies, including (but not

limited to) breast implants and other cosmetic surgeries, hormone replacement therapy, and reproductive technologies (such as the now-infamous Dalkon Shield, diethylstilbestrol, and in vitro fertilization). For the ways in which we think about the silicone breast implant controversy—including what was done well and what was done badly in the courts—can go a long way toward indicating how medical torts should be litigated in court, and changes that may be necessary to ensure women's equal treatment before the law.

In the 1990s, experts testified in court that there are no grave health risks associated with silicone breast implants, contradicting claims made in a class action suit brought by thousands of women against one implant manufacturer, Dow Corning. According to the plaintiffs, who had very similar medical complications (lupus, scleroderma, and other serious connective tissue disorders), the implants themselves caused these life-threatening conditions.⁴ Downplaying the veracity of these experiences in deference to expert testimony is problematic, given that, at the time, silicone breast implants had been virtually untested for serious medical harms. Furthermore, there are procedural concerns about appealing to scientific evidence in the courtroom, including how judges and juries are to differentiate "junk science" from reliable scientific reports. Simply discounting the experience of plaintiffs in light of so-called scientific testimony therefore seems both imprudent and unjust.

I will argue that we need to change litigation practices so that women are no longer at a disadvantage in civil litigation. As I will indicate, women are disadvantaged in tort law by the following conditions: a) most tort litigation involving women centers on medical torts, while torts involving men are usually occupational torts; b) it is far more difficult to prove causation in the area of medical torts; c) data that could prove causation is not available precisely because of manufacturers' failure to adequately test medical products before making them available on the market to women; and d) this leads to a double bind for women, wherein they must prove the company's negligence but cannot because of such negligence. The current structure of tort law means that companies committing medical torts are rewarded for their irresponsibility, since it renders women largely incapable of proving it. Bush's proposed cap may serve to encourage further corporate negligence, since a limit on pain and suffering awards means that companies could take even greater risks in rushing medical products and devices to the market, with full knowledge that the profits would likely outweigh costs of any resulting litigation.

After outlining the ways in which women are unfairly disadvantaged in medical torts, I will make several recommendations to remedy this unfairness. I will argue that we should ease the burden of proof in medical torts by weakening the causation requirement, thus allowing the focus to be less on causation and more on the company's irresponsibility regarding adequate pre-market testing.⁵ These changes in litigation would alter manufacturers' behavior by forcing them to adopt more rigorous testing and risk assessment standards; if more rigorous standards were in place, fewer untested or risky technologies would be available for public consumption.

The Genderedness of Tort Law

Injustices committed within medical areas of tort law are not merely injustices against "the people;" they tend to be more particularly committed against women. As Thomas Koenig and Michael Rustad have argued (1995), any tort reforms should be mindful of the differential impact on women. They claim that remedies to tort law involve a gendered element,

since there is a bifurcation into “his” and “her” areas of tort law based upon gender roles. Women and men use tort remedies in response to different problems: men primarily for workplace injuries (including accidents caused by farm and industrial machinery, vehicles, chemicals, and asbestos)⁶ and women for medical malpractice litigation.⁷

So, for example, women use tort law as a remedy for harms experienced from cosmetic surgeries, from childbirth from other reproductive-related activities, and for neglect in nursing homes. These are gender-based injuries, and hearken back to my earlier claim that many medical technologies have resulted in harms⁸ specifically to women.⁹ Koenig and Rustad further claim that “Women are also far more likely than men to be awarded non-economic damages in medical products liability litigation.”¹⁰ Thus any changes to tort law that pertain to medical devices/products, and that attempt to govern how they are litigated in court, will differentially impact women, and may result in their inability to recover for injuries. And changes to tort law are imminent given Bush’s recent attempts to place limits on punitive damages and the size of non-economic rewards that are awarded by juries. But by being aware of the social and political elements of tort law, we can better appreciate how such changes may harm, not just the individual women who litigate, but all women who may be subjected to the questionable technologies. Furthermore, social and political awareness allows one to see individual women’s complaints as part of broader issues in women’s health care (for example, the extent to which women’s health is put at risk to achieve, not just individual, but culturally-defined “goods”). While one could rightly argue that *all* our values are culturally defined, encouraged, or prescribed, it is important to consider the extent to which serious health risks to women are considered “worth it” for the goals of beautification, reproduction, and aging avoidance. These imperatives are not equally imposed upon men because they are particularly “feminine” values; indeed, women (and womanhood) are defined by them.

Gender is clearly an issue in the silicone breast implant debate, and generally within law. Indeed, gender stereotypes may also play into women’s attempts to seek justice through the law: for, in the implant example, notions of the “good girl” and “bad girl” played into jury decision-making regarding liability verdicts. Consider that out of seventeen implant cases brought to court between 1970 and 1994, plaintiffs prevailed in eleven of them. Of the seventeen cases, twelve were brought by women who had the implants for augmentation purposes; only six of those twelve resulted in awards for plaintiffs. But in cases filed by women who had implants for post-mastectomy purposes, four out of five cases were victorious. The difference in plaintiff awards suggest that, in the minds of jurors, women who sought out breast implants for augmentation purposes were less deserving of compensation than were their cohorts who used the implants for post-mastectomy purposes. But by removing the causation requirement, moral judgments could be placed where they belong: on the manufacturers who make products available. Yet placing such an onus on manufacturers may prove difficult given their political and economic clout.

Corporate Power and Implant Litigation

Businesses like Dow Corning have the power to make alliances with other corporations and organizations to solidify and strengthen their political power. Such power includes the ability to dominate the market, to finance scientific reports and other analyses that advance their corporate viewpoint, to maintain huge lobbying power, and to generally refuse to cooperate with governmental or legal policies.¹¹ For example, after May 1991 when the Food and Drug Administration (FDA) notified

manufacturers that they had to submit their safety data by the following July or have their products removed from the market, the breast implant industry responded with a lobbying campaign that ran well over a million dollars.¹² At their own expense, the American Society of Plastic and Reproductive Surgeons (ASPRS) flew 400 women from 37 states to Washington, D.C. to lobby Congress to keep the implants on the market. And while spending more than a million dollars on lobbying may seem extraordinary, “compared to the \$330 million a year that implant surgery generated for plastic surgeons, it could be characterized as a modest investment.”¹³

Beyond this lobbying power, manufacturers exert control over independent government agencies like the FDA, and there is often a circulation of individuals who move from the regulated to the regulators. As Koenig and Rustad indicate, agencies like the FDA or Federal Aviation Administration (FAA) often make determinations regarding the safety of products by heavily relying on information and data from the very agencies that they regulate (50). As they claim, “...the FDA must rely on the regulated industry for data. In the past few years, the failure of companies to provide crucial data to the FDA for a series of drugs—Merital, Oraflex, Zomax, and Selacyn—has been disastrous for consumers.”¹⁴ If the FDA must depend in large part on research data from the very companies it is regulating, then its independence should seriously be questioned. And the additional problem of employees who shift from the regulated to the regulators arises.¹⁵

Medical Torts, Scientific Evidence, and Problems in Proving Causation

Medical product manufacture has been so badly governed that little testing is required or completed prior to the marketing of medical products. As I am arguing, this poses particular problems for women, who constitute the main litigators in this area. When women litigate over injuries caused by medical products, the scientific evidence provided in court becomes hotly contested. And since judges and juries are often unable to make determinations regarding the scientific validity of experts’ claims, a mechanism has been put in place to aid judges in determining which evidence should be admissible in court.

The precedent-setting 1993 *Daubert* case put forth a new test for determining the admissibility of scientific evidence in court, and turned trial judges into “gatekeepers” who are to keep unreliable scientific evidence from being heard by jurors. This gate-keeping role requires judges to determine a variety of things, including whether the claim that a party seeks to introduce, can and has been, tested, whether the claim has undergone peer review and publication, and whether the claims are generally accepted within the scientific community.¹⁶ According to the Federal Rules of Evidence, judges may appeal to independent scientific experts to receive guidance in making such determinations, since judges often lack the expertise themselves, and they are otherwise left depending on the adversarial parties’ “expert” witnesses. Indeed, this approach has been used by judges who dealt with the issue of breast implants and connective tissue disorders: based on the rules, judges called in “neutral” and “objective” experts to testify as to the connection between implants and grave health risks. However, note that this move, while laudable, still raises problems concerning the possibility of neutrality and objectivity in expert testimony.

But most important in considering the handicaps that women face as plaintiffs in medical tort law is that the burden of proof may be impossible to meet because of the causation standards that are in place. As I am arguing, the causation

requirement places a burden on women litigating medical torts that does not equally apply to men litigating occupational torts. That men fall under occupational areas of tort law may mean that they have greater success in bringing suits to court, since their lawsuits will tend to be more individualized, and causation is more easily determined. For example, suppose that a man who works for the Best Corporation is hurt on the job site: he falls several feet off a ladder, and his back is so badly affected that he is no longer able to work. Imagine further that this worker sues the Best Corporation for negligence because he discovers that his fall was caused by a rung in the ladder breaking, and that the company had failed to meet safety standards by testing their equipment to prevent such malfunction. In such a case, the individual plaintiff may have a greater chance of winning his case, since causation is more easily determined (the Best Corporation's failure to test their equipment caused the worker's fall). By contrast, consider the problems facing women who are involved in medical torts: drugs, for example, are distributed on a mass scale and are often untested. The result is that, as Roger Cramton points out, "Thousands of strangers may be injured by the dissemination and use of a single product."¹⁷ Thus, one finds with medical torts a much greater likelihood that class action suits will ensue, where thousands (or sometimes millions) of claims flow from mass exposure to one product. Where mass torts are concerned, proving causation becomes a serious problem because, unlike the plaintiff in the occupational tort case, plaintiffs involved in a class action suit usually have difficulty determining whether exposure to the product in question caused the alleged injury. Furthermore, unlike the victim who has an immediate physical injury that resulted from his fall, the victims of harmful medical products usually suffer from diseases that have a delayed onset, sometimes a generation after the product was used. As Cramton claims,

Often there is scientific uncertainty as to whether the exposure caused the alleged harm or whether the condition was the result of the individual's conduct (smoking, for example) or the presence of background substances in the natural environment. Frequently, expert witnesses will be able to testify about causation only in terms of statistical probabilities based on scattered or inconclusive epidemiological studies.¹⁸

That men's lawsuits more often concern occupational torts also means that they are bringing suits within an area that has clear standards to which corporations are held. Health and safety standards are outlined so that companies are very clear as to what minimal guidelines must be met to avoid liability. Best Corporation, for example, is liable for failing to ensure that their equipment was in good working order. But medical torts, where standards are overseen by the FDA, are notoriously poorly governed, with few to no guidelines in place that determine whether manufacturers are responsible for failing to meet minimum standards. This means that, in the case of silicone implants, it is difficult for women to prove that manufacturers failed to meet minimum industry standards, since no standards were in place at the time implant surgeries were performed.

The problems regarding gender and causation have resulted in strong disagreements between scholars over the role that causation should play in litigating toxic torts. As I will indicate in what follows, some scholars have argued against the decline of causation, claiming that the courts must maintain high evidentiary standards. Others have contended that causation is the wrong focus in tort law because it acts as a stand in for the real issue, corporate negligence.

The Debate over Causation: To Strengthen or Weaken?

In "The Breast Implant Fiasco," legal scholar David Bernstein (1999) argues that corporations like Dow Corning are imperiled by opportunistic and mercenary class action suits that are often based on sensationalism (especially in the media), "actions by politically motivated individuals and organizations that result in the downplaying of objective scientific inquiry,"¹⁹ public outrage at corporate irresponsibility, and the use of "junk science" to meet the attorney and clients' financial goals.²⁰ Bernstein argues for modifications in tort law that would make it more difficult for plaintiffs to bring suits (including class actions suits) against corporations that have allegedly harmed them. His argument is based on a "trickle down theory:" that the benefits of strict tort laws that set high evidentiary standards will serve big business and trickle down as direct benefits to consumers.²¹ Current laws, he argues, leave defendants in the position where "...in order to avoid potentially ruinous litigation, manufacturers would be deterred...from producing anything that could potentially have any toxic effects, bringing the United States economy to a virtual halt."²² The kinds of modifications he supports include: 1) setting up tribunals of experts to determine what constitutes safe, responsible corporate practices; 2) giving corporations consideration in court for risks they *reduced* (in the implant case, argues Bernstein, Dow Corning reduced risks to women by bringing silicone implants on the market, thus giving women an alternative to direct injection of silicone into their breasts);²³ 3) exempting defendants from liability if they follow the safety practices of government agencies; and 4) a loser-pays system, where, if plaintiffs lose they would pay all court costs (thus avoiding "nuisance suits and speculative litigation").²⁴ Bernstein asserts that the purpose of tort law is to determine whether Company *A* was the cause of Plaintiff *B*'s injury and, if so, to compensate Plaintiff *B* for that injury. But if we cannot determine that Company *A* was the probable cause of her injury, then Plaintiff *B* should receive nothing and, furthermore, Plaintiff *B* should be held liable for all incurred court costs.

Judith Jarvis Thomson's work, while predating Bernstein, takes a similar view on the role that causation should play in tort law. Thomson claims that

...there is yet another way in which causation is important to us in imposing liability: not only do we (ideally) wish liability to be imposed only on those who actually caused the injury, we also are reluctant to attribute causality unless we can see the evidence for it as causally connected with the injury."²⁵

Like Bernstein, Thomson argues that causation should remain foundational to tort law. Although two persons may commit the same careless act, if person *A* causes no harm to another while person *B* does harm, then only Person *B* should be held liable in tort law. The bare difference between the two cases, according to Thomson, is that person *B*'s action caused harm to another while person *A*'s did not. Although we may consider the acts morally equivalent because both acted negligently—both were in breach of a duty of care that is owed to others—there is an important *legal* difference since only person *B*'s negligence caused harm to another.

As I am arguing, the issue of causation in tort law involves not just legal, but moral considerations. Indeed, moral considerations are at the heart of the dispute between theorists who support, and those who reject the centrality of causation to determining liability. Bernstein provides the following example to indicate the importance of the causation requirement:

Negligence alone has never been an appropriate basis for finding a defendant liable in the absence of proof of causation. Even extremely reckless behavior, manifesting a gross indifference to human life, does not by itself create tort liability. For example, let us posit the case of a truck driver who is driving through a school zone at 2:35 p.m., just after school lets out. This driver is driving 90 miles per hour, is very drunk, is on tranquilizers and anti-depressants, is legally blind, and is driving a truck that he knows has shoddy brakes. Miraculously, he doesn't hit any children, and makes it safely to his next stop. What can the current tort system do to punish our driver, and prevent him from engaging in similar behavior in the future? Nothing. As this example shows, despite the general expansion of the American tort system over the past few decades, liability is still based on causation of injury, not just misbehavior.²⁶

Note that Bernstein commits the “is implies ought” fallacy. He assumes that because the tort system currently emphasizes causation, not misbehavior, it ought to be set up in that way. But many critics have rejected this view, asserting that even radical changes to the tort system could be accommodated. For example, Margaret Berger argues that “it is not antithetical to underlying theories of tort law to abolish proof of causation as an essential element of a cause of action. The contrary is true—eliminating causation furthers tort law’s corrective justice rationale that liability is linked to moral responsibility.”²⁷ Berger and other critics thus argue that causation serves as a stand-in for morally responsible corporate behavior, but that given what is at stake, tort law should encourage the morally responsible behavior itself.

Like Berger and others,²⁸ I argue that supporting or strengthening the causation requirement in tort law fails to address the moral question of corporate negligence. But more importantly, causation in medical tort law results in a “catch-22” for women. The courts’ demand that women prove causation *paradoxically renders women dependent upon the non-negligence of companies*. That is, if women (like those embroiled in silicone implant litigation) are to prove that a defendant’s product caused their injuries, they must rely on that defendant having both tested the product prior to placing it on the market, and on having published the results of those tests. In this way, companies are rewarded for their own negligence while women, who must prove the company’s negligence, are rendered powerless to do so because of it.

As many commentators have pointed out, the women involved in silicone implant litigation lacked any rich scientific data to support their claims because companies manufacturing the implants did not do any research before putting the implants on the market. Indeed, only after women became seriously ill and started making claims about lethal harms did the silicone implant industry commence their scientific reviews. Prior to their claims of deadly medical harms caused by the implants, women experienced problems with them, including discomfort, contracture, implant leakage, and hardened breasts, all which failed to produce serious scientific investigation. Though the manufacturers involved in silicone implant and other litigation are “typically in the best position to create the necessary data...its incentives are the reverse.”²⁹ Dow Corning, for example, had little incentive to produce data on silicone-gel breast implants prior to marketing them, since any negative data could be used to prevent their marketing. Even though they risked litigation by rushing their product to the market, Dow stood to gain more from implant sales than what they might have lost due to successful litigation against

them.³⁰ So if the women in the implant litigation appealed to bad science, it is, in part, traceable to the failings of the corporations themselves.

Sindell v. Abbott Laboratories: A Test Case for Eliminating Causation?

I have argued thus far that the emphasis on causation in medical tort law imperils corporate responsibility and leaves women caught in a double-bind of having to rely on research data from the very companies they are suing for negligence. In considering how the relaxation of the causation requirement in tort law might be accomplished, consider the precedent-setting *Sindell v. Abbott Laboratories* case (1980). This case concerns medical torts, and recognizes the great disadvantage at which women are placed if causation is not significantly softened.

Between 1941 and 1971, drug companies engaged in the manufacture, promotion, and marketing of a harmful drug called diethylstilbestrol (DES), a synthetic compound of the female hormone estrogen. The drug was marketed to prevent women from miscarrying their pregnancies; but the serious physical effects of the drug were experienced many years later by the daughters who were exposed to the drug prior to their birth. DES daughters suffered adenocarcinoma, a rapidly-spreading, lethal form of cancer. Judith Sindell was one such DES daughter who in 1980 brought a suit against Abbott Laboratories and other companies that manufactured and marketed the drug. While Sindell could name the drug, DES, as the harm-causing agent, she was unable to name the manufacturer of the product consumed by her mother; yet she sought compensatory and punitive damages for herself from defendants she held jointly liable.³¹ *Sindell* argued that it was unfair and prejudicial to require that the plaintiff prove that Abbott Laboratories (or the other companies named) was the defendant that caused her illness, since the harms done to her occurred *in utero* and manifested themselves a generation after the time her mother took the drug. That Sindell’s mother could not name the manufacturer of the DES she took during pregnancy is also unsurprising given that “DES was produced from a common and mutually agreed upon formula as a fungible drug interchangeable with other brands of the same product; defendants knew or should have known that it was customary for doctors to prescribe the drug by its generic rather than its brand name and that pharmacists filled prescriptions from whatever brand of the drug happened to be in stock.”³²

The court agreed that the plaintiff would be unfairly burdened if proof of causation was required, and shifted the burden of proof from Sindell to the defendants, requiring them to prove that they could not have caused her illness.³³ The case was complicated by the fact that two hundred companies had manufactured DES at the time during which the plaintiff was harmed, and that any one of them could have produced the drug that harmed her. Yet Sindell named only five companies of the two hundred, and defendants argued that “there is no rational basis upon which to infer that any defendant in this action caused plaintiff’s injuries, nor even a reasonable possibility that they were responsible.”³⁴ The court concurred with the plaintiff, however, and took the view that, while one manufacturer’s product may not have injured a particular plaintiff, “we can assume that it injured a different plaintiff and all we are talking about is a mere matching of plaintiffs and defendants.”³⁵

The *Sindell* case was precedent-setting because it severely loosened the causation requirement. Indeed, the plaintiff was not required to show that any of the defendants she named were more than likely the cause of her harm. Following the decision in *Sindell*, critics like Judith Jarvis Thomson argued

the moral and legal problems surrounding the “decline of cause,” claiming that “if cause declines in law, law to that extent departs from morality.”³⁶ Yet, I want to argue the opposite case. If we do not considerably relax (or remove) the causation requirement in tort law, we will be departing from morality by failing to hold companies morally responsible for their reckless, wrongful, or harmful activities, and by barring plaintiffs (women) from seeking legal remedies for grievous harms committed by manufacturers.

In fact, the *Sindell* case may not go far enough in assisting women embroiled in implant litigation or other medical tort cases. Whereas in *Sindell* there was no disagreement that diethylstilbestrol caused the plaintiff’s illness, there is serious controversy over whether silicone gel implants caused the plaintiffs’ ill health. All parties involved in *Sindell* agreed that DES causes adenocarcinoma, and that Judith Sindell’s cancer was caused by the DES her mother took while pregnant. By contrast, there has been little agreement about the causal connection between connective tissue disorder and silicone gel implants. In the *Sindell* case, what I will call first-order causation was established; it was only the second-order causation issue—which manufacturer produced the drug that harmed the plaintiff—that was unsettled. Thus, a weakening of the causation requirement *ala Sindell* would not offer a sufficient legal remedy for women involved in implant litigation. As I will argue below, the courts may need to go beyond *Sindell* to ensure fairness for women involved in this (and other) product litigation.

The Decline of Causation: Some Implications

As I have indicated, critics like Bernstein and Bush would argue that, in light of the unprecedented awards to women in breast implant litigation, we ought to go the other direction to make it even more difficult for plaintiffs to receive massive settlements. They argue that by strengthening the causation requirement, taking a “loser pays” approach, limiting jury awards, and allowing bodies like the FDA to protect corporations from litigation, we prevent these corporations from going bankrupt and ceasing technological development, thus protecting against their “bringing the United States’s economy to a virtual halt.”³⁷ I disagree. That plaintiffs wield such power over manufacturers—and that the demise of a company (like Dow Corning) could mean doom to the entire U.S. economy—is undermined by the reality that, in this case, the breast implant market still exists. Not only has class action litigation over breast implants not caused a collapse of this particular market, but it may have perversely furthered the demands of the market by bringing to light the alleged lack of causation between silicone implants and connective tissue disorders. Indeed, since 1992 there has been a 700% increase in the number of breast implant surgeries, and the numbers are still rising. Bernstein’s slippery slope argument rings false in a market-oriented, risk-assuming culture where corporations exert great influence, both economic and political.

By minimizing the “causation” discourse in the court, we allow room for a different discourse, one that goes beyond the question of scientific expertise to include considerations of corporate (ir) responsibility. While scientific expertise may still be invoked to determine whether a defendant corporation failed to exercise due care, the decline of a causation requirement would certainly allow for deeper considerations of corporate negligence. A minimization of the causation discourse allows the negligibility discourse to establish a different burden of proof that would be easier for plaintiffs to meet. I want to go further than that, however, by making the claim that we must give plaintiffs space in medical tort cases to provide their narratives.

But what should this “narrative” look like? Clearly I cannot argue that women should be given room to testify in court as to the harm caused to them by their implants, since I have already argued that the causation requirement should be minimized or eliminated in tort law. Women should, however, be given the opportunity in court to speak to their experience of illness *and the lack of scientific data available to help them determine the cause of that illness*. In other words, while I am not saying women should be free to claim that silicone implants caused their lupus, I am saying that they should have the opportunity to testify as to what information was available to them when they discovered their lupus, and to indicate the extent to which the manufacturers in question studied the risks of implants prior to their availability on the market.³⁸ In cases where women testify that no scientific data was available, and that this state of affairs exacerbated their fear, panic, and worry (thus causing further deterioration of health), manufacturers would be held liable for causing that state of affairs because of their negligence in failing to properly study the product before its manufacture, and because of the risk at which they put consumers’ lives.³⁹ Opening up the court to plaintiff’s voices would also prevent the aforementioned double bind into which women are placed when they are required to show probable cause, since such a requirement makes them dependent on the research data of the very companies under litigation.

If the causation requirement is to be severely relaxed or abandoned, then it may be necessary to revisit the issue of awards for punitive damages and/or pain and suffering. If plaintiffs are not required to prove probable cause, thus increasing their chances of winning their cases, then Bush’s call to limit awards to plaintiffs may be called for. I would urge that manufacturers be required to pay damages, including fixing the problem their product created, and fulfilling community service requirements, since they should be held responsible to the communities that they harm. Furthermore, Bernstein may be right in this instance that we should prevent lawyers’ “fishing expeditions” by altering the system of contingency fees between plaintiffs and lawyers. But I would not support these stricter measures absent the kind of change to medical tort litigation that I am calling for.

Thus, as I have been arguing, we need tort reform that maximizes, not minimizes, manufacturers’ direct responsibility to the public. In the case of medical products and technologies, where women are particularly at risk, it is appropriate to make corporations responsible for preventing wrongs or harms to women, even if that means certain technologies are not made available at all. While this claim may upset those who take a more liberal stance on the dissemination to the public of new technologies, and those who focus on individual rights above all, I respond that individuals do not have a right to access potential new technologies: indeed, it makes no sense to even talk about such a right. I say this for two reasons: first, because all rights are qualified by law (that is, the law provides us with them, and if there is no right by law then no right exists)⁴⁰ and second, because we cannot have a right to something that does not yet exist. I may desire the development of reproductive technology such that ectogenesis (a “glass uterus”) is available to me, but it makes no sense for me to say that my rights are violated if science does not produce this technology. And furthermore, as David Kessler states, “To argue that people ought to be able to choose their own risks, that government should not intervene, even in the face of inadequate information, is to impose an unrealistic burden on people when they are most vulnerable to manufacturers’ assertions.”⁴¹

Where We Are, and Where We Are Going

In 1992 Dow Corning stopped producing silicone implants; and during the class-action litigation, it filed for bankruptcy. The company just came out of bankruptcy, having settled \$3.2 billion worth of implant claims. But the silicone breast implant fiasco is far from over.

Despite the continuing complications and failure rates associated with implants, on May 10, 2000, the FDA announced that silicone saline-filled implants manufactured by Mentor Corp. and McGhan Medical Corp. will be allowed to remain on the market. The companies are required to provide literature that implant surgeons must give to women so that they can make informed choices prior to implant surgery.⁴² Complications of which women must be notified include risks of pain, infection, capsular contracture, deflation and leakage. The FDA claims that, given the addition of safety information, implants should remain on the market because women want them (*Medical Industry Today*, 2000). But the FDA itself is now cautious about claims concerning these implants: they emphasize that “Women should understand that breast implants do not last a lifetime,” and that “there is a possibility that a substantial number of women who get these implants will require additional surgery to remove or replace their implants because of complications” (*Medical Industry Today*, 2000).

As I argued earlier in this paper, the FDA and other powerful bodies should not allow cultural values—or individual values as expressed by women who desire the implants—to determine what is made available at the social level. Some technologies ought never to have been available to women in the first place, and some (like silicone implants of any kind) ought not to be available now. There is no good argument, other than market demand and the capitalistic push for more products and more technologies, for the continued provision of these implants. On the contrary, despite disavowals of mortal harms caused by silicone breast implants, the non-life-threatening (though still serious) harms caused by them are well-documented. Additionally, the FDA is currently supporting the logically inconsistent position of allowing implants (even those that are silicone gel-filled) for women who have undergone mastectomies and are enrolled in clinical trials while denying them to women who seek breast enlargement for purely cosmetic reasons. One would think that if the implants are deemed unsafe for consumption, they would be ruled unsafe for all consumers, but particularly for women who have survived breast cancer and are being put at additional and unnecessary medical risk.

The implant situation is likely to worsen, not improve, in the near future, as companies lobby to have all restrictions lifted, thus making implants—filled with saline or silicone—freely available to any woman who wants them. The recent avowals that silicone breast implants are not lethally harmful is widely endorsed by the scientific community and is being used to justify widening availability of them. “I have rehearsed some of the justice-based reasons that would warrant the amendment of the causation requirement. The primary reasons are that tort law could reasonably be used to deter corporate wrongdoing and irresponsibility, and that women are unfairly disadvantaged in cases of medical torts by the high standards of the causation requirement.”

Conclusion

In this paper, I offer a rationale for a radical revision of medical tort law. While my focus has been on silicone breast implant litigation, I expect that my arguments will bear on other areas of concern, including hormone replacement therapy, reproductive technologies, and cosmetic surgeries. What was done well and what was done badly in implant litigation may give us cues for future cases (and they are sure to arise) where harms are controversial, highly contested, and civil courts are uncertain about what counts as “good science.” My hope is that the negligibility discourse for which I have argued will take hold in tort law, thus encouraging manufacturers to lessen or eliminate negligent behavior. I have rehearsed some of the justice-based reasons that would warrant the amendment of the causation requirement: primarily, because tort law could reasonably be used to deter the corporate wrongdoing and irresponsibility that results in poor health outcomes and even death, and because women are differentially harmed in cases of medical torts by the high standards of the causation requirement. With these changes in place, there may be moral grounds for considering Bush’s proposed \$250,000 cap in medical tort awards; but it would be unethical to implement it without first correcting these problems.

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Endnotes

1. In a recent speech given in Little Rock, Arkansas, Bush made these and other comments concerning the current state of medical liability. See Bush, 2004.
2. Bush’s claim—that his proposed cap could save \$60-108 billion per year—is based on a 1996 study by Harvard economists Daniel Kessler and Mark McClellan (see Kessler and McClellan, 1996). Their study attempted to measure the cost of “defensive medicine” that is attributable to lawsuits; they determined that, with caps on medical tort damages, health care costs can be reduced between 5 and 9 percent. Yet more recent studies found no strong relationship between the threat of litigation and medical

- costs: for example, the estimated savings have been denied by nonpartisan agencies like the Congressional Budget Office (see Beider and Hagen, 2004) and the General Accounting Office (see US General Accounting Office, 1999).
3. For some excellent critiques of the American health care system, see Kuttner (1999) and Fisk (2000).
4. Note that while scientists claim there is no connection between such potentially lethal diseases and silicone breast implants, there has been no question (either by scientists or the courts) that these implants cause other harms. For example, suits have been successfully brought against implant manufacturers for capsular contracture of fibrous tissue surrounding the breast (hardening of tissue surrounding the implant), muscle pain, and infections caused by the implants, as well as ruptured implants.
5. I will herein focus entirely on tort cases involving corporations, since the current debate about medical tort law focuses almost exclusively on implications for individual physicians. Yet a \$250,000 cap has important implications for patients who are in conflict with corporations, since setting this cap without making deep changes to the system of medical tort litigation will serve to even further disadvantage plaintiffs, and to encourage even more risk-taking on the part of corporations.
6. Koenig and Rustad cite the following statistics: “Males are 29 times more likely than females to be injured by a fall from a scaffold or ladder. Males are six and a half times more likely than females to die from firearms accidents. Five times as many males as females drown. Females are only one-fourteenth as likely as males to drown in boating” (35). Furthermore, as they indicate, even where men are harmed by household products, the products usually correspond to gendered tasks, such as lawn fertilizer, industrial glue, and saws (39).
7. Thomas Koenig and Michael Rustad, “His and Her Tort Reform: Gender Injustice in Disguise,” *Washington Law Review* (January 1995): 2.
8. Here I want to make a distinction between “harms” (that is, physical harms) and “wrongs.” For I do not want to argue that a woman who has not experienced any physical problems in connection with her silicone breast implants has been harmed; I would want to claim, however, that she is wronged by the corporations who made them available on the market without adequate testing and information. If I have implants but do not suffer any ill effects, then I am not harmed by the manufacturer; but certainly I am wronged by them.
9. As evidence of harms to women, consider Lucinda Finley’s (1993) claim that, “Many modern product liability disasters have involved products used almost exclusively by women, often in connection with reproduction—the anti-nausea drug thalidomide, which produced horrifying birth defects; the drug DES, which causes cancer and infertility; the IUD Dalkon Shield, which was sometimes fatal and frequently caused sterilizing pelvic inflammatory disease; breast cancer devices, which can cause serious auto-immune system diseases such as lupus or can permanently disfigure a woman; the acne-treatment drug accutane, which if taken during early stages of pregnancy produces serious birth defects” (11).
10. Thomas Koenig and Michael Rustad, “His and Her Tort Reform: Gender Injustice in Disguise,” *Washington Law Review* (January 1995): 2.
11. Thomas Koenig and Michael Rustad, “His and Her Tort Reform: Gender Injustice in Disguise,” *Washington Law Review* (January 1995): 28-29.
12. Roberta Altman, *Waking Up/Fighting Back: The Politics of Breast Cancer*. (Boston: Little Brown & Co., 1996), 255.
13. *Ibid.*
14. Thomas Koenig and Michael Rustad, “His and Her Tort Reform: Gender Injustice in Disguise,” *Washington Law Review* (January 1995): 50-51.
15. For example, Newspapers report that three FDA employees who reviewed Monsanto’s new bovine growth hormone drug had previously been working with the firm. The Government Accounting Office (GAO) investigated the issue of conflict of interest. Although the GAO concluded there was a technical conflict of interest, it cleared the FDA employees (Koenig and Rustad, 49 n.206).
16. Rebecca Dresser, “Science in the Courtroom: A New Approach,” *Hastings Center Report* 29, no. 3 (May 1999): 26.
17. Roger Cramton, “Individualized Justice, Mass Torts, and ‘Settlement Class Actions’: An Introduction.” *Cornell Law Review* 80 (May 1995): 815.
18. *Ibid.*, 816.
19. David E. Bernstein, “The Breast Implant Fiasco.” *California Law Review* 87 (March 1999): 460.
20. For another detailed account of the problems in tort litigation as they relate to silicone breast implants, see Angell (1996).
21. David E. Bernstein, “The Breast Implant Fiasco.” *California Law Review* 87 (March 1999): 504. Bush echoes Bernstein’s “trickle down theory” in claiming that a cap on pain and suffering awards in cases of medical torts would benefit everyone. As he sees it, the large sums awarded by juries to plaintiffs are having a devastating effect on the health care system, by driving up costs of malpractice insurance for doctors, by encouraging the practice of “defensive medicine,” and, as a result, causing a sharp rise in health care costs. Bush does not, however, hold the insurance industry responsible, and he does not address the way in which the for-profit American health care system encourages litigious behavior.
22. Bernstein, 505.
23. Here Bernstein creates the fiction that Dow actually cared about risks to women in marketing their implants. Yet there is weighty documentation that Dow marketed their breast implants with full knowledge that they might be harmful to women. See, for example, Byrne (1996), and Altman (1996).
24. David E. Bernstein, “The Breast Implant Fiasco.” *California Law Review* 87 (March 1999): 508.
25. Judith Jarvis Thomson, “Remarks on Causation and Liability,” *Philosophy and Public Affairs*. 13, no. 2 (Spring 1984): 132.
26. David E. Bernstein, “The Breast Implant Fiasco,” *California Law Review* 87 (March 1999): 504.
27. Margaret Berger, “Eliminating General Causation: Notes Toward a New Theory of Justice and Toxic Torts.” *Columbia Law Review* (November 1997): 2119.
28. Consider, for example, articles by Wagner (1997) and Feldman (1995).
29. Margaret Berger, “Eliminating General Causation: Notes Toward a New Theory of Justice and Toxic Torts.” *Columbia Law Review* (November 1997): 2131.
30. Indeed, since scientific research takes time to complete (sometimes years), and the harms associated with products often don’t surface until years after consumers use them, companies have an incentive to take risks with consumers’ lives in the meantime.
31. Thomas Koenig and Michael Rustad, “His and Her Tort Reform: Gender Injustice in Disguise,” *Washington Law Review* (January 1995): 3.
32. *Ibid.*
33. This move was based on a preceding case, *Summers v. Tice* (1948). The plaintiff, Summers, was accidentally shot in the eye by defendants, Tice and Simonson, but since the defendants shot at the same time, Summers was unable to name the liable party. The court allowed Summers to hold the two defendants jointly liable, and required Tice and/or

- Simonson to prove that they could not have been the cause of the accident.
34. Thomas Koenig and Michael Rustad, "His and Her Tort Reform: Gender Injustice in Disguise," *Washington Law Review* (January 1995): 9.
 35. *Ibid.*, 19.
 36. Judith Jarvis Thomson, "The Decline of Cause." *Georgetown Law Journal* (October 1987): 599-609.
 37. David E. Bernstein, "The Breast Implant Fiasco," *California Law Review* 87 (March 1999): 505.
 38. Note that this same issue arose in the *Sindell* case. There was much discussion in the court surrounding the degree to which the defendants had failed to discover or warn of the dangers of DES.
 39. One may wonder what grounds a manufacturer would have for determining if it has done enough research before placing a product on the market. If, for example, a woman claimed she became HIV positive because of her implants, would the manufacturer, who had not studied the connection between HIV positivity and silicone implants, be responsible because it did not test for it? Where do we draw the line on manufacturer responsibility? In such cases, we can appeal to principles of reasonableness and foreseeability—whether it is reasonable to expect the manufacturer to have tested for it, and the foreseeability that such a harm would be caused by the product.
 40. Here I am merely suggesting that, while we can speak of "natural rights" or "inalienable rights," such rights are empty apart from laws that define and enforce them.
 41. David Kessler, "The Basis of the FDA's Decision on Breast Implants," *New England Journal of Medicine* (June 18, 1992).
 42. This raises a whole other issue concerning whether doctors will present the literature to women upon consultation in their medical clinics. If physicians are not completing informed consent procedures with women prior to implantation surgery then they, too, are responsible for post-implantation harms experienced by the women. This is a controversial issue that I cannot possibly address within the confines of this paper.