



## The Promise (the Tyranny?): Some Observations on the Evolution of Evidence-Based Medicine

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*“She don’t lie, she don’t lie,  
she don’t lie—COCHRANE!”*

(Refrain from the song “Cochrane” performed by Argentinean physician and Cochrane reviewer, Agustín Ciapponi, at the 2003 Cochrane Colloquium end-of-conference social event.)

A little more than ten years ago a working group at Canada’s McMaster University suggested evidence-based medicine (EBM) as a new approach to teaching and practicing medicine (Evidence-Based Medicine Working Group 1992). EBM is defined as “the conscientious, explicit, and judicious use of the best evidence in making decisions about the care of individual patients” (Sackett 1996: 312). That foundational quote illustrates why EBM carries legitimized political and professional capital among all health care stakeholders, including medical educators, clinicians, patients, governments, and third party payers. EBM is anchored in the grand narrative of modernist scientific medicine. Under the best circumstances, EBM employs science’s empirical testing and measuring tools to free humankind from old fogysm, all the while remaining firm in the belief that this numbered knowledge of the world produces tangible benefits. Lured by this siren’s song of modernity, who can resist the seduction of applying the *best* science to effectively and efficiently address health needs?

EBM is indeed a new medical paradigm. Although there remain outliers still dubious of its utility, my reliable crystal ball tells me that there is a very promising future for the EBM endeavor, especially for high quality EBM work such as that produced by the Cochrane Collaboration, the *ACP Journal Club*, the *Journal of Evidence-Based Health Care*, and the like. That being said, it’s not surprising that relatively rapid, large-scale implementation of EBM has exposed contextual application issues requiring attention.

These issues include the ongoing problem of *phronesis*, i.e., how to best wed patient-oriented evidence to clinical expertise and judgment; how to effectively extrapolate information from population-based randomized clinical trials and apply it to the individual patient; how to steer the international biomedical research agenda and associated EBM to effectively address prioritized international health needs; and how to incorporate qualitative data into the EBM equation (a task that is being undertaken by the nascent the Campbell Collaboration). In an effort to continually improve EBM, those physicians, biomedical researchers, biomedical statisticians, medical librarians, and policymakers who enthusiastically promote diffusion of this innovation have addressed these and related dilemmas as they emerge; as such it is not my intent to speak to those issues here.

Instead, I will consider the evolution of EBM from the dual perspectives of anthropology and my past life of birth activism. The first (anthropological) perspective allows me to critically

examine influential social dynamics within the health care delivery system, paying close attention to the distribution of power in social relations, in clinical authority, and in knowledge production. The complexities of social location and social interactions shape our perspectives and perceptions of the world around us, influencing what we see as risks, as problems, and as solutions. Here, I examine the influence of social context on the evolving practice of EBM.

My second reflexive perspective draws on my long history of birth activism—subtitled “Everything I know today I learned in childbirth preparation classes.” In the 1980s I taught a renegade style of childbirth preparation class. In place of teaching the customary (for the day) Lamaze-style breathing gymnastics, which taught women to be obedient patients, I instead instructed pregnant clients on rebellious strategies to minimize their chances of having an unnecessarily medicalized birth experience. I should add here that I retrospectively view that goal as simplistic and naïve. My clientele included a demographically-skewed, disproportionately large number of physicians, medical residents, medical students, and nurses. As a consequence of their professional orientation, this group was notably conversant with what might be considered rather esoteric medical knowledge. In short, while their social location did not quite equalize the usual provider/patient power differential, it certainly influenced their relationships with their chosen physicians. A curious dynamic emerged.

Not uncommonly, my medical-professional clientele desired a manner of demedicalized birth management that differed from standard institutional hospital fare—such as a desire to avoid an episiotomy, or to birth in something other than the “flat on your back” lithotomy position. Given their relatively privileged insights into the medical world, and knowing that they faced likely resistance from their provider, these pregnant professional women recognized the need to support their unconventional protocol requests in a conventional fashion. They thus armed themselves with supporting medical research, practicing a nascent sort of evidence-based patient choice (Edwards & Elwyn 2001).

They guessed correctly. Their providers did indeed often respond defensively, manifesting a “biased assimilation effect” – described by psychologists as one’s tendency to look harder for flaws in research with which one disagrees. Seeking weaknesses in the women’s proffered research articles, their providers would cite medical research to support their own routinized medical protocols. A patterned thrust and parry of data vs. data ensued. The metaphorical duel was usually called to a draw when the provider successfully assumed authoritative power with statements such as “if you’d seen what I’ve seen” illustrated with a sufficiently convincing worst-case scenario, or more simply “this is the way I do it.”

I offer this dated description of such fractious confrontations to illustrate the dynamic, complex, and relational nature of knowledge production, the subjectivity of scientific medical research in the clinical context, and the socially-located trump card of professional authority. In this 1980s climate, the parallel knowledge base, summarized here as “birth *works*” was considered by providers to be woefully ignorant of *real* medical matters. Social theorist Pierre Bourdieu (1980) would use the term *habitus* to describe the function of power relationships within this state of affairs. According to Bourdieu, *habitus* is the social location, the social lens, and the accompanying social structure, that enables an individual to perceive activities in a particular order and in a particular way, and to evaluate them accordingly. The more one is enmeshed within one’s *habitus*, the more they then conceptualize, interpret, and make sense of surrounding structured activities through that lens. *Habitus* subtly shapes a tacit tolerance for the status quo and is in turn structured by it (Callinicos 1999: 292-3).

In truth, at the time, neither the birth *works* nor the standard medical model had been sufficiently evaluated by a systematic review of medical research to adequately establish where

the weight of the evidence lay. Fast forward to the end of that decade and enter the EBM research data organization and application tool.

EBM disciples will be familiar with the following piece of the EBM origin myth. Epidemiologist and visionary founding father of EBM, Archie Cochrane, suggested that modern obstetrics in particular deserved the “Wooden Spoon Award” for including a multitude of routine clinical interventions lacking a sufficient, scientifically tested, evidentiary base to justify their practice, and whose hazards were unknown (Cochrane 1979). As a response to “Archie’s” clarion call, a collaborative multinational working group set about the task of systematically identifying and evaluating research on childbirth management. The results of their work, published in the two-volume *Effective Care in Pregnancy and Childbirth* (Chalmers, Enkin, & Kierse 1989), demonstrated that critically appraised research supported a social model of childbirth management (birth works) over the standard medical model. Yet, as we know, standard medical management continues to define and shape hospital birth.

Equally relevant to this discussion is the observation that most pregnant women actively seek medically managed hospital birth. Advocates of patient-oriented evidence-based decision-making suggest that patients can and should be effectively engaged in certain aspects of clinical decision-making (Edwards & Elwyn 2001). Available access to EBM databases might potentially lead to increased democratization of what was formerly professionally-owned esoteric medical knowledge. But habitus also influences socially embedded patient consideration of what constitutes best care.

To illustrate, in an attempt to minimize unnecessary and costly routine pregnancy and childbirth intervention, a government-subsidized pilot project in the United Kingdom made EBM-based pregnancy and childbirth decision-aide leaflets available both to pregnant women and to their midwife providers. The leaflets encouraged a balanced consideration of routine interventions. End-of-project evaluation concluded that these decision aides were ineffective in deterring an escalating reliance on technological intervention. At a fundamental level, the information leaflets convinced neither midwives nor consumers that less, in the form of technologically-mediated medical management, might be equally good if not in some cases, better (Stapleton, Kirkham, & Thomas 2002). Like the aforementioned knowledge production, the clinical encounter is equally dynamic, relational, and complex. While EBM has the potential to democratize medical decision-making, resultant EBM patient choice is profoundly manufactured and shaped by habitus including, especially, the influence of popular culture.

So what are we to make of such disconnects? Perhaps modern society's relationship to health care services is similar to its relationship with shopping. In his book *I Want That! How We All Became Shoppers* (2002), cultural historian Thomas Hine observes that shopping practices reflect our sense of entitlement for increasingly sophisticated commodities. Hine tells us "Shopping is a responsibility, an exercise of power. . . . The choices that we make about these things play a big role in determining who we are. We don't want to surrender such power to a computer program. . . ." (p. 208) By comparison, perhaps media-steered health care consumers, and industry-influenced health care providers alike, perceive the most recent medical technologies as delivering optimal care. Encouraged by popular representations which equate "newer, bigger and more" with better, perhaps we selectively view ourselves as entitled to pick and choose among various health services - health care resource thresholds notwithstanding. Quite possibly, we will be unwilling to surrender such consumer power to the vagaries of EBM number crunchers. Patient-oriented EBM be damned?

Alternatively, perhaps the aforementioned blindness is caused by "cognitive bias" which gives an illusion of validity - discounting information that goes against one's preferred conclusion. One can hypothesize that EBM might offer a valuable corrective here - it has the

potential to objectively assess the cumulative merit of the research, and with such an objective assessment, produce robust knowledge to counter cognitive bias. And in certain cases, EBM has done just that. My colleague Howard Brody reminds me that located within EBM's lore there is the pivotal Cardiac Arrhythmia Suppression Trial (CAST). Here, despite plausible pathophysiological reasoning on the soundness of administering antiarrhythmia drugs encainide and flecainide for survivors of myocardial infarction, definitive outcome evaluation demonstrated otherwise. The CAST study found that even though such therapy successfully suppressed asymptomatic or mildly symptomatic ventricular arrhythmias, it ultimately accounted for a higher total mortality (CAST 1989). In this case, outcome data clearly impacted treatment; it triumphed over cognitive bias and successfully influenced subsequent clinical management.

So just why is it that doctors and patients sometimes capriciously discard a working hypothesis because of new data, while at other times they cling to a hypothesis despite evidence to the contrary? Nineteenth-century philosopher William James posited that one set of looks can indeed overcome another way of looking. But he also noted the countervailing tendency. "Most of us grow more and more enslaved to the stock conceptions with which we have once become familiar, and less and less capable of assimilating impressions in any but the old ways. Old fogyism, in short is the inevitable terminus to which life sweeps us on. Objects which violate our established habits of 'apperception' are simply not taken account of at all; or, if on some occasion we are forced by dint of argument to admit their existence, twenty-four hours later the admission is as if it were not, and every trace of the unassimilable truth has vanished from our thought" (James 1950, c 1918).

In the case of childbirth management, EBM-supported reasoning is sacrificed to pragmatic reasoning that sees truth in its consequences. Returning to my *birth works* example, it is casually observed that medicalized childbirth results in healthy mothers and healthy babies, so it is concluded that medicalizing *birth works*. The prevailing medical gaze interprets childbirth as risky; the resultant cultural prescription then views birth as in need of precautionary "just in case, just to be safe ..." medicalization. According to this popular cultural metanarrative birth does not work; it is instead an untidy experience that predictably flirts with disaster, and only when aided by bigger and presumably better medical technologies and more intervention does it then emerge triumphant.

Problematically, reliance on the body of systematic reviews of relevant research argues more convincingly for how to proceed with medical interventions than whether to proceed with them in the first place. This curious paradox is linked in part to human nature, and human perception. "If people want to believe there is an effect, it can be very hard to persuade them that any effect is too small to be important" (Alderson & Groves 2004: 473).

Yet another confounding obstacle to implementing effective and efficient EBM policy is the powerful influence of stories - especially those stories with "tragic outcomes...[that] seem to offer a solution" (Newman 2003: 1426). In his article "*The Power of Stories Over Statistics*" epidemiologist and biostatistician Thomas Newman describes the compelling power of stories, noting how an especially poignant story might make statistical probabilities excessively vivid, and in so doing, inadvertently distort the appropriate application of the statistical data (Newman 2003: 1426). This dynamic might partially explain why the American College of Obstetricians and Gynecologists has recently been willing to entertain the notion of patient choice for elective primary cesarean section (Bump 2002: 823).

The 2003 Institute of Medicine report *Health Professions Education: A Bridge to Quality* suggests that "it is critical for interdisciplinary health teams and each of the disciplines to be able to tap this evidence base effectively at the point of patient care, determining whether an intervention, such as a preventive service, diagnostic test, or therapy, can be expected to produce

better outcomes than alternatives - including the alternative of doing nothing (emphasis mine)" (Institute of Medicine 2003: 56). Ironically, EBM's pattern of reliance on the results of randomized controlled trials focuses the discourse more on doing something than on doing nothing. Thus, it is the case that the medical management model as well as societal opinion are equally biased towards action over inaction.

Returning to my example, childbirth management screening, testing, and measuring are socially and medically reified as the best way to know birth, and within this empirical model a parallel *birth works* model lacks equivalent authority; it is viewed as backward, less desirable, and unsafe. As two general practitioners cogently point out "perhaps it is societal opinion (for which one ear of the medical profession is always pricked) that sins of omission are more reprehensible than errors of commission that is at fault. Is missing a rare diagnosis so much worse than harm from over-testing?" (Doust & Del Mar 2004: 474). The social response appears to be a deafening "yes."

While early EBM argued for a social model of childbirth management, a review of current childbirth management practices demonstrates that EBM failed to effectively challenge societal opinion. Paradoxically, expanding reliance on randomized controlled trials to empirically know birth, such as is required by EBM, now subtly but surely steers birth towards an increasingly medicalized model - the tyranny?

Perhaps my concerns about the evolution of EBM are accurate only when considering unnecessarily medicalized aspects of life and quite possibly EBM is the very best corrective that we have to offer in that epistemological regard; but in today's increasingly medicalized world I simply don't trust that we can accurately distinguish the difference. Medical facts and social values are intimately intertwined. Medical science is dialectical, structuring societal opinion while in turn being structured by it.

As I ponder my benefit-burden, promise-tyranny misgivings about EBM, I realize that my reservations resemble those presented by Susan Sontag in her essays *On Photography* (1966). I conclude with the following pastiche, lifted - and ever so slightly twisted - from Sontag's essays.

- Like photography, EBM is "a way of depersonalizing our relation to the" patient (p.167).
- Like photography, "it is a way of appropriating the objective world" (p.122).
- Like photography, EBM "can be seen as a faithful recording of what is evident" (p.118).
- Like photography, "it is a way of finding a place in the world ... to relate to it with detachment" (p.167).
- Just as photography turns living beings into things, so, too, EBM turns embodied processes of the doctor-patient interaction into commodified things, things to be measured and recorded (p.98).
- EBM "creates another habit of seeing - both intense and cool, solicitous and detached, charmed by the insignificant details, addicted to incongruity/congruity" (p.99).
- In photography it is only by looking at reality in the form of an object does it become real. So too, EBM requires that aspects of a healing encounter be subjected to testing, measuring, and within such a robust numbered equation, the option of "doing nothing" pales by comparison (p.168).
- Like photography, EBM "cannot create a moral position, but [it] can reinforce one and can help build a nascent one" (p.17).
- Like photography, EBM "may be more memorable than moving images, real people, because [it is] a neat slice of time, not a flow" (p.17).
- EBM is in "a chronic voyeuristic relation to the world which levels the meaning of all events" (p.11).

- To reduce an aspect of the healing encounter to the level of a systematic review is to "appropriate" [it]...It means putting [it] into a certain relation to the world that feels like knowledge-and, therefore, like power" (p.4).
- EBM "alters and enlarges our notions of what is worth looking at and what we have a right to observe. [It is] a grammar and, even more importantly, an ethics of seeing" (p.3).
- EBM "can convey some kind of stable meaning, [it] can reveal truth" (p.106).

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## SB 764

by Tom Tomlinson

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*MHR* readers will be interested in tracking the progress of Michigan Senate Bill 764, introduced in the Fall legislative session and referred to the Committee on Family and Human Services. The bill would amend the state probate code to provide special protections for a fetus being carried by a legally incapacitated person. Specifically, the bill provides that:

1. If medical care, treatment, or service for a legally incapacitated individual presents a risk of injury to or death of an unborn person, the legally incapacitated individual's guardian shall report that risk to the court. The court shall appoint a guardian ad litem to represent the interest of the unborn person.
2. If he or she accepts the appointment under this section, the guardian ad litem shall investigate and make a recommendation concerning the medical care, treatment, or service. The guardian ad litem shall make a report of the investigation and recommendation in writing or recorded testimony.
3. A person who has possession or control of information, reports, or records regarding a legally incapacitated individual shall give a guardian ad litem appointed under this section access to the information, reports, or records.
4. A guardian ad litem appointed under this section may engage legal counsel and do whatever is necessary to defend and protect the interests of the unborn person.

At present, Michigan's durable power of attorney for health care statute (Act 386 of 1998) stipulates that its provisions "cannot be used to make a medical treatment decision to withhold or withdraw treatment from a patient who is pregnant that would result in the pregnant patient's death." This does not mean that Act 386 makes such decisions on behalf of an incapacitated pregnant woman illegal. It implies only that such a decision would not enjoy the liability protections provided by Act 386. And Act 386 provides no further legal guidance on how decisions for incapacitated pregnant patients should be made.

The proposed Senate bill would fill this legal vacuum with the assumption that the interests and rights of an unborn child are at least potentially on a par with, and might supersede, those of the incapacitated person. This is a principle that would readily be accepted by those with right-to-life convictions, and such convictions are no doubt what motivates the sponsors of this bill. However, even those who generally support the right to choose abortion might be able to envision circumstances when the stakes for the incapacitated person are so low, and the stakes for a viable fetus are so high, that the interests of the fetus might plausibly take precedence, at least in the absence of any previously-expressed wishes of the patient to the contrary. Imagine, for example, the situation of a pregnant patient, near term, who is now comatose and near death. Unless there was evidence that she would refuse such interventions, sustaining her on life

support long enough to improve the chances of the baby's intact survival seems an ethically reasonable course of action.

The question is whether such possibly acceptable applications of the proposed law can justify its passage. We have to consider what its implications would be when it is applied to the whole range of situations in which incapacitated pregnant women might be placed. Some of those are very worrisome. One has to do with the potential interference with a woman's right to control her medical treatment. To make the previous scenario even remotely plausible for those without right-to-life convictions, I had to stipulate that we had no evidence regarding the patient's wishes in the matter. What if she had expressed her wish to have treatment stopped under such circumstances, or her patient advocate in good faith represented this as her view? The Senate bill wouldn't require that these wishes be ignored. But it would require that their implementation be delayed pending the appointment of a guardian *ad litem*, the guardian *ad litem*'s investigation, and the eventual outcome of a probate court hearing. This delay becomes even more troubling if we consider that the patient may not be comatose, but alert enough to be suffering the effects of her illness and its treatment.

Such threats to the patient's rights and interest arise not only in situations when treatment should be withdrawn, but when it should be provided. Imagine a pregnant developmentally disabled woman with a court-appointed guardian who is diagnosed with an aggressive cancer, which requires treatment with chemotherapy and radiation which pose risks to normal fetal development. Here a delay might well compromise the prognosis for this patient's successful treatment.

In so obstructing the protection of *incapacitated* women's rights and interest, the bill sets up a double standard. At least so long as *Roe v. Wade* stands, adult pregnant women with legal capacity don't have to prove to a court that their decision to have an abortion, or to accept or refuse medical treatment, duly protects the best interests of their fetus. It's hard to imagine an acceptable ethical reason for singling out decisions for incapacitated women for special legal scrutiny. Is it that as a rule, being incapacitated, their rights and interests are less compelling than those of competent women, and so more likely to be plausibly overridden by the interests of the fetus? But decades of court cases, from *Quinlan* on, have taught us that their wishes are equally deserving of respect, where they are known. And surely, their interest in avoiding pointless suffering, and in preserving health and function, is equally strong.

The cynical might conclude that the sponsors are hoping we competent citizens won't much notice or care what happens to incapacitated citizens. Those who do care should keep an eye on SB 764.

(To track health-related legislation, go to [www.MichiganLegislature.org](http://www.MichiganLegislature.org). The site allows you to set up a free account that will notify you of legislation being introduced.)



## Conflict of Interest- A Crucial Issue for Academic Medicine

by Howard Brody

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In 1994, Gordon Rausser, an economist, became Dean of the College of Natural Resources at University of California-Berkeley (UCB). Frustrated by the erosion of state funding—his college received only 34 percent of its budget from the state—he decided aggressively to pursue corporate money. The end result was a 5 year, \$25 million deal between the giant pharmaceutical company Novartis (through an agricultural products subsidiary) and UCB's Department of Plant and Microbial Biology. In exchange for this support, Novartis received first rights to negotiate for any license from patented discoveries resulting from faculty research.

In May, 2000, the California Senate held hearings on the Novartis deal. “Dean Rausser was asked the following: Suppose a professor who has signed a confidentiality agreement comes across data that represents a serious danger to the public and wishes to speak out as a matter of conscience. Will UCB come to the scientist's aid? The answer was unambiguous. The university had no obligation to defend scientists who break the contract, even if there is a public interest in revealing information.” (Sheldon Krinsky, *Science in the Private Interest: Has the Lure of Profits Corrupted Biomedical Research?* New York: Rowman and Littlefield, 2003, p. 37).

Rewind the tape now to 1982. Donald Kennedy, president of Stanford University, convened an invitation-only conference at Pajaro Dunes (on the Monterey Peninsula in California), bringing together top administrators and scientists from the most prestigious American research universities with executives from 11 major corporations. The goal was to develop guidelines to manage the relationship between the corporate world and the academic scientists.

‘It is important that universities and industries maintain basic academic values in their research agreements,’ their draft statement declared. ‘Agreements should be constructed, for example, in ways that do not promote a secrecy that will harm the progress of science, impair the education of students, interfere with the choice of faculty members of the scientific questions or lines of inquiry they pursue, or divert the energies of faculty members from their primary obligations to teaching and research.’... Within a few years, every one of these supposedly sacrosanct tenets of ‘basic academic values’ had been violated. They were trampled in the stampede to stake a claim in what science reporter Nicholas Wade called ‘the genetic El Dorado.’ (Linda Marsa. *Prescription for Profits: How the Pharmaceutical Industry Bankrolled the Unholy Marriage Between Science and Business*. New York: Scribner, 1997, p. 133.)

The conflicts of interest created by the increasing reliance of academic science—particularly biomedical science—on the largesse of industry have created a real danger of the erosion of the core public service mission of the university, and of the public trust that academic scientists now

enjoy. The university has tended to respond to this threat with both eyes firmly fixed on the mirage of the city of gold in the distance. Don't worry about conflicts of interest. They can be managed. Arthur Schafer, writing about the ethics of this relationship, compares the university dean or president deciding whether to sell off an academic department to Novartis, with the practicing physician deciding whether or not to accept gifts from the pharmaceutical company sales representative:

Doctors seldom admit that their clinical judgment has been influenced by the acceptance of lavish dinners, free laptop computers, or skiing holidays to Vail, Colorado. Top university and hospital officials strenuously deny any suggestion that the receipt of donations or research funds from drug companies has skewed in any way their performance of their duties. Nor do they believe that a university's ownership of patents in new drugs being tested at the university could potentially undermine the rigour with which the university polices the integrity of the research carried out under its aegis.

'I can't be bought for ... (fill in the blank: research funding, major donations, ... laptop computer, fancy dinner....)' Employing these or similar words, [all] confidently affirm that there is no harm done—certainly not to their own integrity—by the acceptance of drug company beneficences." Arthur Schafer, Biomedical conflicts of interest: a defence of the sequestration thesis—learning from the cases of Nancy Olivieri and David Healy. *Journal of Medical Ethics*, 2004: 30(1): 20.

Schafer forces us to confront the possibility that the same thing that is true of practitioners may be true of academic administrators. As is increasingly shown by empirical research, medical practitioners tend to be readily influenced by drug company gifts and other contacts, and remain largely clueless that they are subject to influence. University administrators may be similarly in denial about the threat to academic values posed by feeding at the corporate trough. One form this denial frequently takes is the promulgation of conflict of interest policies within universities to govern conflicts that occur among individual faculty members who own stock in, or have lucrative consulting or speaker fees from industry. Universities have been much slower to develop conflict of interest policies that govern the entire university and its top administrators, though the UCB-Novartis example makes clear that there is potentially far greater danger at that level.

I take very seriously the signs that greet me when I drive onto this campus to go to work every day, proclaiming that this is the "pioneer land grant university." I take this to mean among other things that MSU cannot exist in a state of pristine academic purity, and that we must strive to address the real problems that affect the people of Michigan. This inevitably means that we must seek collaborative relationships with industry. Schafer, in his thoughtful analysis, points out that collaborating effectively with industry to be sure that academic discoveries actually go out to benefit the general public need not necessarily imply that academics take their funding directly from industry. Indeed, he calls for the creation of additional forms of what are commonly called "firewalls" in industry funding of academic research. I suggest that anyone arguing for the maintenance of the status quo read Schafer's article carefully and be required to indicate exactly where his analysis goes off track.

Two sets of folks must accept responsibility for the present state of affairs. One is we, the academic community. We have allowed our greed (sorry, I can't think of a kinder word) to blind us to the real dangers of the relationship that has slowly developed over time, to the point where we cannot rely on scientists at a state university to warn us of clear and present dangers posed by

agricultural chemicals because their department has been “sold” to the company that makes the chemicals. The other group who must accept blame is we, the American taxpayers. We have allowed our greed (sorry, I can’t think of a kinder word) to persuade us that we can have all the benefits of living in a modern, technologically advanced society while paying far less in taxes, proportionately, than is paid by the citizens of virtually every other highly developed nation. In the process, along with allowing our public health infrastructure to fall apart and denying more than 40 million fellow citizens access to medical care, we have been willing to auction off our universities to the highest bidder. Sadly, neither group today seems willing to admit that we are part of the problem.



## The Researcher's Bill of Rights

by Harry Perlstadt

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The time has come to restore a reasonable balance between the interests of researchers and the powers of Institutional Review Boards (IRBs). The purpose of federal policy for the protection of human subjects is to protect potential subjects from harm by allowing them to make informed decisions about the risks of participating in a research project. This policy is implemented through a set of independent IRBs composed of faculty and community members with the unfettered power to interpret and enforce the federal regulations at 45 CFR 46.

With encouragement and directives from the Office of Human Research Protections (OHRP), IRBs have expanded their authority over university community members and thereby may abridge First Amendment rights of peaceful assembly, speech and the press (which undoubtedly include oral presentation and publication of scientific knowledge and applications). No effort has been made by OHRP or IRBs to clarify where the constitutional rights of researchers end and where university powers begin. While IRBs exercise their power in the name of research subjects' interests, there is no protection against the risk that IRBs will develop constraints on inquiry and publication that are responsive to the university's political constituencies and monetary interests.

The *Belmont Report* noted that research usually involves the scientific method, that is, a set of procedures designed to reach that objective. The general rule was that research—defined as activity designed to test a hypothesis, permit conclusions to be drawn, and contribute to generalizable knowledge—should undergo review for the protection of human subjects. But the procedures in social research inquiries are commonly no different from ways of associating with people, inquiring about their lives, and writing about society that do not require prior review and possible censorship. This is true for a wide variety of social research, from phone surveys and focus groups in corporate market research and political campaigns to ethnographic and other qualitative forms of research, which frequently merge with journalism. The First Amendment does not speak of “journalism” and makes no exception for “research” in the liberties it guarantees. The human research protections system has evolved without regard for constitutionally-protected forms of assembly, speech and publication, creating a chilling effect on academic freedom and legitimate scientific inquiry.

The very indifference of OHRP and IRB administrators to the political values they threaten indicates the gravity of the situation. Given the diversity and multiplicity of universities in the U.S., it is inevitable that, without strong protections, some IRBs will use “the interest of research subjects” as a guise for restricting research that is not injurious to subjects but that is offensive to social and political constituencies deemed crucial to the university's institutional well-being. Such institutional conflicts of interests should not apply when determining claims that a given form of inquiry should be modified or restricted because of the danger it poses to subjects.

Unfortunately the human research protections review process yields decisions that are inconsistent within and across IRBs. An example of inconsistencies within IRB is that one researcher was allowed to advertise a \$25 payment for participation on a campus flier but another researcher was explicitly told not to put any payment amount on the flier. An example of across IRB inconsistencies is that the Centers for Disease Control have received a waiver enabling them to use “passive consent” whereby students and youth will receive the CDC Youth Behavior Risk Survey unless parents or guardians say no but most IRBs will not grant such a waiver for similar or even identical surveys and the Office for Human Research Protections insists that “passive consent” is not permissible. In most cases any appeal of such decisions is internal to the IRB, with no oversight or review by other faculty committees or university officials.

Some IRB’s require researchers to obtain documented informed consent for asking the very same questions that journalists, market researchers or public opinion pollsters can ask by properly identifying themselves and informing the respondent that answers may become part of a public record or report. Similar problems arise for researchers observing public behavior that is often videotaped or photographed by the media.

In addition, IRB’s may set higher standards than required by state law. For example, if a state law permits verbal consent to receive treatment and has provisions for the release of aggregate data with proper confidentiality provisions, it not only seems unfair, but an override of state law for IRBs to require a researcher to contact every patient and only use the data from those who sign release forms.

Finally, it is not the intent of federal policy to dictate acceptable methodologies or prevent lousy research. It is to prevent harmful research. This important distinction is often overlooked in an attempt to shield subjects from what is defined as poor or unnecessary research.

A Researcher’s Bill of Rights is essential.<sup>1</sup> In addition to whatever conflicts of interest may exist for researchers vis-a-vis research subjects, the conflicts of interest that exist for IRBs by virtue of their institutional location must be taken into account. The proper framework for thinking about these issues is not the simple triad of researcher, research subject, and IRB but one that includes the university’s various institutional interests and the American constitutional tradition of rights and due process. The disciplinary and professional associations of scholars and researchers must begin to counterbalance the institutional interests of universities.

This suggests that both Universities and disciplinary and professional associations should develop a policy statement addressing the rights of researchers with respect to human research protections. Such a Researcher’s Bill of Rights would include the following provisions:

- 1) Researchers and evaluators shall have the right to be told of the waivers to documented informed consent contained in 45 CFR 46 and have the waivers considered on the basis of precedent and existing waivers for federal agencies conducting similar research using similar methods on similar subjects.
- 2) Researchers and evaluators have the right to use data collected by state agencies under human subjects provisions governing those agencies and IRBs cannot set a higher standard than state law or rules nor insist that researchers get additional documented informed consent from each client if the agency has already obtained it.
- 3) Researchers and evaluators shall have the right to claim their research is exempt from IRB review under existing federal regulatory criteria except insofar as the source of funding specifically requires IRB approval of the exemption.
- 4) Researchers and evaluators shall have the same rights to associate with and observe people, ask questions, and publish the information they acquire as does any person

whose rights of assembly, inquiry, and publication are protected by the First Amendment of the U.S. Constitution unless the receipt of funding for research specifically requires prior review and approval of research procedures.

- 5) Researchers and evaluators have the right to fair and uniform procedures and to due process, including having decisions based on precedent and consistent from case to case and from university to university, receiving written reasons for decisions, and the ability to appeal decisions to a neutral third party.

#### **NOTES**

1. The Researcher's Bill of Rights was created with the help of Jack Katz, Department of Sociology, University of California— Los Angeles.



## Center News & Announcements

7th Annual National Undergraduate Bioethics Conference, University of Michigan, Ann Arbor, MI (Mar. 19-20, 2004). Speakers included **HOWARD BRODY, LEN FLECK, FRED GIFFORD, HARRY PERLSTADT, TOM TOMLINSON.**

### **JUDY ANDRE**

- Spoke at the Biomedical Ethics Unit at McGill University in Montreal, on “Virtue and the Global Village: Honesty in Public Health” (Mar. 2, 2004).
- Spoke at the Centre D’Ethique Clinique, Cochin Hospital, Paris, on “Bioethics as Practice” and her current work, “Cosmopolitan Virtue” (Mar. 25, 2004).

### **HOWARD BRODY**

- Participated in an ethics consultation seminar, “Ethical Issues Regarding Physicians and the Pharmaceutical Industry,” Texas A&M University, Salada, TX (Feb. 9, 2004).
- Presented “Ethical Implications of Placebos,” as part of a panel discussion at the meeting of the American Association for the Advancement of Science, Seattle, WA (Feb. 14, 2004).

### **LEN FLECK**

- Member of a panel discussing “Sibling Obligations in the Age of Genetics” for the Philosophy and Medicine Committee of the American Philosophical Association at their annual Eastern Division meeting in Washington D.C. (Dec. 27-30). The paper that was the basis for his presentation, “Sharing Genetic Information: What is a Minimally Decent Sibling to Do?” is being published in the Spring, 2004 issue of the American Philosophical Association Newsletter on Philosophy and Medicine.