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got health care? lucky you!

by Steve Heilig

San Francisco is making a unique move: attempting to resolve the terrible problem of so many persons without health insurance. This is a problem that has baffled our nation. It's hard to find a reasonable and compassionate person who argues that anyone should not have access to health care. The arguments begin when we talk about how to ensure that everyone does have access—and especially, who should pay for it.

There are now more than 40 million Americans without health insurance. That does not necessarily mean they have no access to care, but it does mean that, when they get sick, they will find numerous barriers to seeing a doctor, and however they do

so, via emergency rooms or otherwise, their care is likely to be even more expensive and episodic than otherwise. Resultant delays in seeking and attaining care can result in sicker people and worse outcomes. Add the fact that the United States is both the wealthiest nation on earth yet the one with the most uninsured people, and you have a situation fraught with ethical dilemmas.

Some of the best minds have proposed many and varied solutions to the issue of the uninsured. None have yet to succeed. National plans have flamed out, aborted by private

lobbying, ideology, bureaucratic inertia, and real concerns about workability. State proposals, such as one just vetoed by California's governor, have yet to attain any real political feasibility. Piecemeal local efforts, such as public hospitals, "free" community clinics, the charity of individual clinicians and donors all soldier on, picking up the pieces of the dysfunctional non-system.

San Francisco is currently trying something different—a universal health care program that will provide access, if not insurance, to every resident of our city. What might that mean? Who will benefit, and who will pay? What are the chances it will work?

Join us for a forum on those questions Wednesday, November 29, 5:30–7:30 p.m., at University of Pacific, School of Dentistry, 2155 Webster Street, Room 308; directly across from the CPMC Webster Street building. The moderator of the panel will be Mark Smith, M.D., CEO of the California Healthcare Foundation and a veteran of the local and previous national efforts to attain this goal. Representatives of the medical, business, and other groups will participate, along with Mayor Gavin Newsom.

For information and to RSVP, contact Antonio Kruger at 415-600-1647.

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The Ethicist Is

by Albert R. Jonsen, Ph.D.



Several weeks ago, I was given the bad news that I have Parkinson's disease. I am 72 years old and have been, fortunately, in good health all my life. At present, my symptoms are a mild tremor in my right hand, slight rigidity in facial muscles, occasional stumbling and a couple of sudden, bad falls. My primary care doctor referred me to a neurologist, who confirmed the diagnosis of early Parkinson's. She honestly informed me that there was no cure but that there were some drugs that alleviate some of the early symptoms of the disease. Then she told me that a new drug was being developed that showed some promise of actually retarding the progression of the disease. She asked whether I would be interested in joining what she called "a clinical trial" that was enrolling persons like myself who had not yet received any of the current drugs. Here is my question: what do I need to know to give an informed answer? I have seen many newspaper stories about research going wrong, even with fatal results. Also, a friend told me that even more dramatic research was being done involving stem cells and that I should look into that.

"Clinical trial" is medical terminology for medical research that attempts to test the safety and usefulness of new drugs by a carefully organized plan of comparing the effects of the drugs administered to persons who volunteer. This form of medical research is essential to modern medicine, since its progress in treating patients requires that all drugs and treatments developed in the laboratory be eventually



tested in human beings. Since the 1960s, all clinical trials take place in a strictly regulated system. Scientists seeking federal grants from the National Institutes of Health, and pharmaceutical companies intending to submit new products to the federal Food and Drug Administration, must observe a set of federal regulations.

Every institution where research is done must have an Institutional Review Board (IRB). Every proposal for research (called a "protocol") must be submitted to the IRB, which reviews it for soundness of scientific design, for the risks and benefits associated with the pro-

posed treatment (based on similar experiences and on laboratory and animal studies) and the explanation of the research that must be given to the participants before they are accepted as volunteers. Failure to go through this procedure, or ignoring its recommendations, can have serious consequences for researchers. Most major institutions require all research, not just the research seeking federal funding or approval, to meet these requirements.

The first question to ask your neurologist is whether the clinical trial has been approved by an IRB. That

approval assures that careful consideration has been given to the design of the research, the qualifications of the researchers and the risks and possible benefits. The most important thing to understand about clinical trials is that the “benefits,” almost always, come to future patients, not to those who volunteer for the trial. It is an American habit to respond positively to the word “new,” expecting that “new” means “improved.” The doctor’s presentation may, even unintentionally, suggest this. Thus, persons asked to volunteer easily assume that they are getting something “better.” However, the precise point of the trial is to discover whether the new treatment is, in fact, better, and that discovery comes through careful analysis and comparison of many effects of the drug, in many patients. In fact, most clinical trials are “randomized,” that is, the volunteers are randomly divided into two groups, one of which is given the test drug, and the other either an extant drug or a “placebo.” A placebo is a substance that looks like the test drug, but has no actual effect on the body—these used to be called “sugar pills.” The treatments are coded and neither doctor nor patient knows which is being given. At the end of the trial, the code is opened and the effects on each group are measured and compared. Of course, even during the trial, volunteers are closely observed for any ill effects.

So, far from being a new and improved treatment, the researcher is offering you an opportunity to contribute to better treatments for future patients. Of course, if the test drug does have positive value, those who have received it may benefit, but this is serendipity. The negative side of this serendipity is the danger that some unknown feature of the test

drug, or the non-effects of the placebo, might be harmful. This is what usually ends up in the media stories that we see about clinical trials. For example, several years ago, the media reported that a young man, Jesse Gelsinger, volunteered for a trial of a genetic therapy for a disease that he had in a mild form. After the treatment was administered, he had a fatal reaction and died. The reaction, in less serious form, had occurred in several previous volunteers but was not considered important enough to tell Jesse. However, it was later noted that the researcher had some financial interest in the success of the trial and may have been motivated to refrain from giving negative information to his volunteers.

Some drug trials are sponsored by drug companies that pay very substantial fees to physicians to enter their patients in the trial. This creates a conflict of interest, tempting the physician to “fudge” a bit on criteria for admission to the detriment of the patient. Also, as in the Gelsinger case, a physician may be an owner or investor in the firm testing the treatment and thus have a financial interest in positive test results. We are now much more careful about identifying such conflicts of interest. The IRB looks for them and you should ask the researcher, if he or she does not bring this sensitive topic up.

If you are interested in being a volunteer, you will be given a consent form. This document, reviewed by the IRB, states the risks and benefits as best they can be known. You may find the document daunting. You should not hesitate to ask for clear explanations. Often, a large trial will have a coordinator whose job is, in part, to assure that participants are clearly informed. When you sign the consent form, you are not “signing away” any rights but merely affirming that you

understand the nature of the trial and that you are freely volunteering. You can revoke your consent at any time.

You mention “stem cell” experiments. Stem cells have been in the news a great deal these days, and confusion reigns about them. The majority of media stories have focused on the dispute over embryonic stem cells, which are obtained by destroying a human embryo—opponents find this morally reprehensible. Parkinson’s is often mentioned as one of the eventual targets of a stem cell therapy. Currently, this sort of stem cell research, which is very promising scientifically, is far from application to humans. Other forms of stem cells, such as the cells derived from bone marrow, are already used for treatment of many cancers. Another form of stem cells, derived from adult organs and tissue, or from chord blood, are currently being studied for human use in some conditions, including Parkinson’s, but with little effect. A decade ago, there was some enthusiasm about implanting fetal cells in the brains of Parkinson’s patients. Several clinical trials were done, but the results were disappointing and the research terminated.

Your neurologist’s invitation offers you a wonderful opportunity to advance medical science and, perhaps, to be on the “cutting edge” of progress in combating a devastating disease. But you have the right to be fully informed about all aspects of this study. Your acceptance should be motivated by generosity rather than impelled by desperation. Even if you yourself may not benefit from the study, many others who suffer from the disease that presently afflicts you may be the beneficiaries. This is, for many, a powerful motive to volunteer.



After Action Report

Andereck Lecture Series



Dr. William Andereck continued taking his ethics lectures on the road. In September, he was the keynote speaker for a

conference at El Camino Hospital in Mountain View and presented a review of all ethics cases reviewed by PMHV. During early October, he gave a lecture for the Geriatric Psychiatry nursing staff, then later in the month presented "Ethical Issues at the End of Life: transitioning to End of Life care in the ICU" at Seton Medical Center.

BAB

The quarterly meeting of the Bay Area Bioethicists convened on the 28th of September for their final assembly this calendar year. The group has several new members as it continues to grow and promote itself to ethicists throughout the region. Participants are asked to discuss their work and research at their home institutions and solicit ideas, feedback and collaboration from the others. This group serves as an information repository and clearing house for the many Bioethicists in the Bay Area. September's meeting featured a special guest, the Program's visiting scholar Dr. Lawrence J. Schneiderman, who led a presentation and group discussion on futility.

Talk Ethics: Should Doctors Obey the Law? The role of law in clinical decision making.

On November 2, PMHV continued our successful *Talk Ethics* series by again having a specialist speak on an apropos topic that marries well with ethics. In July, it was Dr. Steven Miles speaking about medical involve-

ment in torture. On this occasion, University of New Mexico School of Law Professor Robert Schwartz led a discussion of mostly medical residents and law students. For a recap of the evening, please visit our website.



Jonsen Lecture Series

Dr. Albert Jonsen did his part by sharing his ethical expertise throughout the state. In

early September, he spoke about ethics at a seminar put forth by Kaiser Permanente, then traveled to an ethics talk at the Daughters of Charity Health System in Newport Beach. By the end of the month, he had returned home to give a lecture at the Pediatric Pharmacy Conference in San Francisco.

Ethics Seminar for Psychiatry Residents

Dr. Steven Reidbord, a psychiatrist and member of California Pacific Medical Center's ethics committee, led an ethics seminar for second and third year psychiatry residents, as he does every other year. These eight sessions, which took the place of departmental grand rounds during the summer, focused on the principles of ethics, such as justice and autonomy. The residents, most of whom had no prior ethics training, attended one hour per week and received required reading between class sessions. Topics covered included involuntary commitment, informed consent, suicide, and conflicts of interest.



In the News

Media Blitz

Andereck KPIX Interview: On August 22, Dr. William Andereck was interviewed by Dr. Kim Mulvihill of local CBS news affiliate KPIX channel 5, regarding a John Muir Physician Network memo that called for changes in colonoscopy screening procedures. Dr. Andereck shared his belief that there is no point in doing screening for diseases that are not expected to develop within the remaining life expectancy of a particular patient.

Andereck AMA News Interview:

In September, Dr. William Andereck was asked by the *American Medical Association News* to give his opinion on practicing medicine outside of managed care; how can you do it? His response was, "to provide patients with personal attention and quality medical care."

Andereck Chronicle Op-Ed: On August 6, the *San Francisco Chronicle's* Sunday op-ed page featured an edited version of Dr. Andereck's opinion piece. For a copy of the entire article, contact Antonio Kruger at 415-600-1647.



On the Calendar

Andereck Cardiology Rounds

In August, Dr. Andereck began weekly Rounds in Cardiology, replacing his ICU Rounding. ICU Rounding will be suspended in order to avoid compromising our research program on the role of ethics intervention in the ICU.

PMHV to Host Meeting of Journal Editors

February 15-17, 2007

PMHV will bring together for the first time editors of the leading bioethics journals published in English. Chaired by Dr. Albert Jonsen, Co-Director of PMHV, the meeting will be the beginning of what is anticipated to be an on-going association of the editors working together to develop and disseminate “best practices” guidelines for publishing in

bioethics journals. Journals that will be represented at the meeting include: *Cambridge Quarterly of Healthcare Ethics*; *American Journal of Bioethics*; *Bioethics*; *Hastings Center Report*; *Healthcare Ethics Committee Forum*; *IRB*; *Journal of Clinical Ethics*; *The Journal of Bioethics*; *Journal of Medicine and Philosophy*; *Kennedy Institute of Ethics Journal*; *Nursing Ethics*; and *Theoretical Medicine*. Plans are underway for a second meeting in June 2007 to be held in London.

International Bioethics Retreat 2007

Saint Catharine's College Cambridge University, England, will be the site for the next International Bioethics Retreat to be held **June 18-22, 2007**. The Retreat, co-sponsored by

PMHV and Chaired by Co-Director Dr. William Andereck, offers a group of invited experts in medicine, philosophy, law, and health policy the unique opportunity to present their current research to colleagues from around the world for discussion and critique. These interchanges not only expand cross-cultural understanding, they often lead to establishing international projects and visiting scholar exchanges. Every year new countries are represented at the meeting. To date bioethicists have come from: Australia, Bulgaria, Canada, Finland, France, Germany, Grenada, Israel, Italy, Poland, the Netherlands, Spain, Switzerland, South Africa, Russia, Croatia, Serbia, Sweden, the United Kingdom, and the United States.



Program Projects

Researching Residents' Moral Reasoning

This year was the twelfth year in continuing Dr. Andereck's research on the moral reasoning of residents. For over a decade, Dr. Andereck has been tracking the way residents reach moral decisions in regards to patient care. Previous studies suggest that residents' moral reasoning stops advancing after a certain point in development. Dr. Andereck hypothesizes that this isn't so and that the instruments used to measure reasoning in the previous studies were flawed. So far, his research affirms his hypothesis.

Chief Medicine Resident as Adjunct Faculty

Last year's Chief Medicine Resident Lina Illic will be staying on as adjunct

faculty with the Program. Lina will focus her time mainly at the Palo Alto Medical Foundation, but will return to California Pacific to lecture the residents on a variety of ethics topics. Lina was very successful last year in engaging her peers in ethics discourse and problem solving. It is because of this that the Program asked her to stay. We're very happy to have Lina and her teaching talents with us again.

Cambridge Quarterly

The *Cambridge Quarterly of Healthcare Ethics* is the international bioethics journal published by Cambridge University Press and edited in PMHV by Thomasine Kushner and Steve Heilig, along with editorial board members William Andereck and Albert Jonsen. From time to time, issues of

special relevance to readers of *Ethical Times* will be highlighted here.

“Bioethics and War” is the timely subject for the Fall issue of CQ. Authors in this special volume explore the challenges for medicine as doctors and other health professionals weigh their responsibilities as caregivers against their obligations as citizens. The topics covered range from an historical overview of ethics, medicine, and war; the role of physicians in the development of chemical and biological weapons; the use of torture to elicit information needed to protect citizens; and the implications of metaphorical depictions of medicine as war and war as medicine.

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Stop Talking Medicaese

Patients and their families frequently meet with doctors and nurses to discuss the medical issues that arise during a hospital stay. Frequently, the clinicians use terms that may not be clear to patients. In the Winter 2006 issue of *Ethical Times*, we presented the beginning of a list of some of the more commonly used terms and defined them in patient friendly words (we hope). Here are three more terms to add to the list. The complete list will be available on our website at www.cpmc.org/ethics.

Code status: A medical term that states whether procedures called CPR

should be used when a patient's heart stops or they stop breathing.

Full code: In the event of sudden failure of the heart or lungs, the medical team will use aggressive measures including CPR to restore heart and lung function.

Do not resuscitate (DNR): The decision by a patient or appropriate decision makers not to use the methods of cardiac resuscitation to restart heart beat and breathing. If these methods are not used, the patient will quickly die.

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