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Democratizing the Gene Age

By Gregory Fowler

The practice of science in the twenty-first Century will be different. *Application* is fast becoming the dominant operative term. In light of the Human Genome Project (HGP) - the $3 billion, fifteen-year effort to identify and map the 100,000 genes and three billion chemical building blocks that make up Human DNA - the stuff of science fiction doesn't seem so fanciful anymore. "Genome science" will continue to touch off new waves of debate over the ethical and social implications of the application of such feats as "nuclear transplantation" and eventually human germ-line gene therapy. In the process, concerns, fears, misperceptions and misconceptions among the public are fueled while the experts ponder legislative alternatives. How ought the debate over these issues be structured? In his book, *Coming to Public Judgment: Making Democracy Work in a Complex World*, Daniel Yankelovich asserts that "...the eroding ability of the American public to participate in the political decisions that affect their lives is threatening the expression of the American Dream, the Dream of self-governance."1 Richard Sclove echoes that sentiment in his book *Democracy and Technology*: "...people should have a say in the technological decisions that affect their lives."2 Indeed, almost twenty years after molecular biologists convened the Asilomar Conference to consider the social implications of recombinant DNA - and the creation of the Ethical, Legal and Social Implications Program of the HGP in 1988 - the issue of "doing science in the public interest" is still with us.

With its deliberate commitment to identify the ethical, legal, and social implications (ELSI) of its own scientific progress, the HGP is a powerfully illuminating model for how to promote public understanding of science and technology suited to a new style of policy making by a participating citizenry. Toward achieving that objective, nine scholars - drawn from the disciplines of genome science (Glen A. Evans), bioethics (Eric Juengst), education (David Micklos), anthropology/biology (Fatimiah Jackson), communication (Celeste Condit), ethics/health care (Michael Garland), biotechnology (Burke Zimmerman), theology (Ronald Cole-Turner), and public policy (Mark Frankel) - were convened as a panel to discuss "The Human Genome Project: What's The Public Got To Do With It?" as part of the AAAS Annual Meeting in Seattle, Washington last February. The focus of the all-day Symposium was to lay a foundation for exploring substantive approaches and strategies for stimulating public dialogue that produces relevant data about public values and stimulates widespread enhancement of citizen responsibility for the policy choices associated with HGP-related interventions. More specifically, the symposium was designed to offer multidisciplinary perspective on two questions about the HGP: 1) which consequences of the availability of the human DNA sequence will affect the public? and 2) what measures should be taken to prepare the public for that eventuality? In the process, the symposium sought to answer the layman's question, "What has this got to do with me?" and, more fundamentally, "Is educating scientists to respond to the concerns of the public doing science in the public interest?"

Trying to put some definitional constraints on the label, "the public," was our first order of business. A month-long pre-symposium cyberdiscussion among all nine panelists and the two conference organizers delivered only one consensus on that label: that no one definition is adequate. The range predictably mirrored the disciplines of the panelists. From the social sciences side of the panel came such definitions as: "A broad spectrum of individuals who share their values and social narratives to the construction of a social discourse;" and "All those whose common good is bound up in the mutual dependency and shared authority of a democracy." On the other end of the spectrum, the natural scientists defined "the public" as "the U.S. taxpayer" or that public constituency who is "paying for the

generation of this information and its deposition into the public domain." In general, the panelists' collective view of the public, which needs to be kept "broad and inclusive," comprises a wide spectrum of individuals who share their values and social narratives to the construction of a social discourse. The various subsets of the "many publics" include: ethnic and religious communities, extended family members, and the current and prospective users of technology. The size, composition, education and financial security of each will predictably play a role in the type, level and quality of participation in discourse about the HGP.

On the basis of everyone's ability to carry on some kind of discourse, in the panel's view "the public" is, then, "everyone" especially those who should play a role in shaping how society should deploy technologies and the information correlated with them. In other words, "The mothers and fathers and sisters and brothers and neighbors and strangers who live in the communities where genetic events occur and genetic 'fixes' offer hope and fear."

The second major aim of the Seattle Symposium was to shed light on some real-time strategies for involving the public in the policy-making process concerning the application of HGP-related technologies. A synthesis of a few panelists' remarks suggests that this process will require at least three-steps: 1) identification and connection with "public values" through public discourse; followed by 2) a channeling of those values through the proper "receptor site(s)" into 3) the policy-making process. But how to accomplish these goals generated much discussion among panelists and the audience.

"Create a public scandal," "Insult some group," "Get written into a prime-time script" would certainly "get the ball rolling" in the view of one of the panelists. As we have observed in the past, media sensationalism can provide a useful springboard for generating major public discussions of science policy. In addition, the media admirably serves as the means for creating a "lay constituency" and a "lay cause" dedicated to achieving its ends through protest.

While effective in the short term, protest strategies are not useful for laying the foundation on which *sustained discussion* and understanding of issues can be built within the lay community. Stimulating a well-informed conversation where many voices are heard and all reasonable perspectives are given due consideration - a process aimed at empowering the individual participant to think for him or herself - is a much more potent learning tool. These horizontal discussions are designed to build a partnership between experts and the general public. Public fora and traditional surveys were not considered by many of the panelists to be effective means to this end. "Remediation does not lie in technical experts constructing artificial debate venues, pumping the participants full of technical information, and then taking dictation from the outcome." What is needed, in the words of one of the panelists and co-founder of *Oregon Health Decisions* (a civic organization dedicated to facilitating public participation in health policy issues in Oregon), is a shift from "trying to educate the public (communication from scientists and lawyers toward the public)...to...finding out about [or exploring] the public's values relative to a specific policy issue." This will involve three broad goals: 1) education, 2) transfer of information, and 3) nourishing the sense of the American community weakened by "hyper individualism," "alienation from political life," "cynicism about politics and power," and "a feeling of being voiceless in political matters." Confirming the challenge which lies ahead is the sobering statistic that 53 percent of the public agree that "...because of their knowledge, scientific researchers possess powers that make them dangerous."3

Several of the panelists emphasized the critical aspect of "education" as central to the process of achieving "scientific literacy," inferring that a basic understanding of the HGP by the public would be required for meaningful participation in any policy-making decision regarding its application. That this process should be concentrated in the primary and secondary school curriculum, in lieu of strategies designed for the extant adult population, was one of the Symposium's more hotly-debated issues.

There is no doubt that enhanced science education in the primary and secondary schools is a major key to the challenges of helping to reinvigorate "participatory democracy" in this country, and with regard to the HGP, to change our thinking about science, in general, and (the new) genetics, in particular. However, in the long-term, it is not prudent to design strategies that leave the adult laity, including those drawn from all ethnic communities, out of the conversation. In the view of one panelist who has collected survey data to gauge perceptions of genetic determinism in U.S. society, "Substantial segments of the [adult] public are capable of making critical judgments and independent interpretations and valuations of the HGP." In that "communitarian" sense, the electric shock given to the implanted

egg which ultimately became "Dolly the Sheep" may have simultaneously reawakened the necessary link between science and society. Indeed, that single experiment may have been more effective in engaging *average citizens* in a public debate about genome science than the $8 million spent each year since 1991 by the HGP's Ethical, Legal, Social Implications Program. Is there a lesson here? In the words of David Cox, a member of the newly-created National Bioethics Advisory Commission, "Just because something is scientifically right and proven, it isn't the end of the story. You have to consider how that fact is going to be parlayed into people's lives."4

The Symposium raised a long list of concerns, any one of which would warrant at least another full-day session: 1) The widening gulf between the "technocrat class" and "the lay public"; 2) Communicating increasingly complex scientific information to a scientifically-illiterate public; 3) Insuring the equal representation of ethnic minorities in the HGP sequence data to be included in the reference taxonomic description of *Homo sapiens sapiens*; 4) The need for ethicists and genetic counselors to integrate better the religious (moral) concerns with the ethical decision-making process regarding the use of information from HGP-related diagnostic procedures and, of course, 5) Ensuring that "public values" will not be systematically overlooked by any alternative for involving the public in the policy-making process.

Ironically, it was the issue of how to define, and meaningfully use, the term "public values" and the relationship of "values" to the decision-making process that generated the most discussion among the panelists and produced the least consensus. Of "opinions," and "attitudes," "values" are the most stable, enduring, and fundamental of the three categories of "public opinion." "Facts" and rationally-projected probabilities are what we want to leave to scientists. It is only for "values" - those qualities in the world that attract or repel one - that we want to go to the public. As one panelist mused, "A difficult word, all in all."

If the Symposium did nothing else, it once again underscored the need for better communication between the scientific and the non-scientific communities. In the words of one panelist, "The 'scientifically proficient' don't trust 'the others' to be able to get it all straight enough to have anything sensible to say about public policy affecting either research or its applications. The 'scientifically-illiterate' don't want to parade their ignorance and keep quiet and direct their discussion toward 'values' since that is what they can bring to discussion of the 'ethical, legal, and social implications' of the HGP. The general public stays passive, keeps quiet, hopes for good things, or fears bad things depending on which popular journals they read or other media they use to nourish their minds."

The Human Genome Project is scheduled to close up shop in 2005. And when it does, ELSI's activism on behalf of "public interest science" may shut down as well. Enhancing the practice of democracy in the name of making social responsibility for the common good of our community a substantive task, a possible task, a reasonable task, and a shared task between the genome scientist and the "general public" will then fall to us. However difficult this will be, it is an exercise absolutely critical to the (re)building of an effective, engaged and democratic citizenry - without which the "American Dream" of self-governance will never be fully realized. As one audience member remarked at the end of the day, "I came here expecting to once more hear about the myriad of issues raised by human genome research. Instead, I walked into a real public debate. We need more of these at scientific meetings."

Endnotes

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4. Allen, A. "Gene Machine: Can Anyone Control the Human Genome Project?" *Lingua Franca*, March, 1997, p. 33.

IN THE NEWS

British Insurers Announce New Genetic Testing Policy

The Association of British Insurers (ABI), which represents 440 insurance companies that sell nearly all of Britain's life insurance policies, has announced a new policy on genetic testing. When applying for life insurance, disclosure of a genetic test result has always been a requirement. The new ABI policy statement softens this situation somewhat. People applying for a life insurance policy up to $160,000 linked to a new mortgage will still be required to reveal the results from a genetic test, but if the test results are positive, these will be disregarded rather than used against the applicant. The information collected will be analyzed to assess whether it might be used to determine the degree of risk that subsequently arises in relation to the outcome predicted by the test so that insurers can gauge any financial impact on their company. No one will be required to take a genetic test when applying for life insurance. The policy will be reviewed after a two-year period. Some British medical and consumer groups have expressed concern over how the genetic information collected will be used. And several large insurers have announced that they are not planning to ask whether potential customers have had a genetic test. Others, however, have pledged to offer reduced premiums to those who disclose a negative test for a genetic disorder.

NIH/DOE Reassess ELSI Genome Program

A specially appointed joint NIH/DOE committee to evaluate the Ethical, Legal, and Social Implications Program (ELSI) of the Human Genome Project has recommended changes in the Program's structure and responsibilities, which it characterized as "much too broad to be satisfied by any single body." The Committee acknowledged "the importance to public accountability of providing an independent evaluation and review of ELSI issues," yet recognized that "it may not be possible to have a totally independent critique of federally-sponsored research housed within the federal government." Nevertheless, the committee observed that its recommendations are "intended to assure so far as possible that there is open and unfettered review of genetic research and the social consequences of that research." The Committee made three basic recommendations: 1) an ELSI Research Evaluation Committee be established with responsibility for oversight of the extramural ELSI grant portfolio; 2) an NIH-wide process should be instituted to coordinate ELSI activities undertaken by the intramural genetic research programs at NIH; and 3) an Advisory Committee on Genetics and Public Policy should be set up in the Office of the Secretary of the Department of Health and Human Services to assist in the development of public policy resulting from advances in genetics. The NIH National Advisory Council for Human Genome Research discussed these recommendations at its February 20 meeting in Bethesda, MD, where the chair of the current ELSI Working Group expressed support for the recommended measures and suggested that its present members collectively resign so that the new Research Evaluation Committee could have a fresh start. Some members of the Advisory Council urged that ways be found to incorporate more public input into the process of assessing ELSI issues, while others emphasized the importance of ensuring some coordination and integration among the three levels of government that the recommendations address. The Council will consider specific proposals on how to implement the recommendations, especially with regard to the organization and functioning of the ELSI Research Evaluation Committee at its May meeting. The DOE advisory committee will also review the report's recommendations at its next meeting. (The full report can be found on the World Wide Web at http://www.ornl.gov/hgmis/archive/elsirept.html.)

Dolly Goes to Washington

The recent news of the successful cloning of a sheep not only prompted the President's issuance of a temporary ban on federal funding for human cloning research and a call for a voluntary moratorium on private funding for such research. It also inspired Congressional committees of both the Senate and the House to host hearings in March on cloning.

Scientists identified many benefits and uses of this technology: more efficient processes of animal husbandry; a deeper understanding of the turning on and off of genes in the early stages of embryo development; production of human proteins by farm animals via genetic insertion and replication ; and the manufacture of human cells for transplantation.

Ethical concerns expressed included fear of the disruptive power cloning could exert on the family structure, especially

if it were used to replicate dying or deceased children, as well as worries about increasing tolerance for genetic variation, and thus those with genetic disabilities. The importance of recognizing the impact of environmental influences on human development was a also common reminder. Legal issues included the possible unconstitutionality of a federal ban on this research and the lack of regulations regarding current reproductive technologies.

Both hearings brought announcements of proposed legislation. Sen. Christopher Bond (R-MO), concerned about potential ethical infractions, announced a bill (S. 368) to prohibit the use of federal funds for research involving human cloning. Rep. Vernon Ehlers (R-MI) introduced an equivalent bill (H.R. 922), as well as a second (H.R. 923) , making the production of a human clone illegal.

The National Bioethics Advisory Commission (NBAC), which was charged by President Clinton to conduct a review of the legal and ethical issues raised by the cloning research and to recommend possible actions to prevent its abuse, reporting back to him by late May, held a hearing on March 13-14. The hearing focused primarily on religious concerns surrounding cloning and genetic research, with perspectives presented from a variety of religious traditions including Roman Catholicism, Judaism, and Islam.

Common themes that emerged from these perspectives included potential effects on notions of individuality, and further worries about the impact of cloning on the family. Other religious concerns included the sovereignty of human beings in relation to God and other creatures, and the spirituality involved in the customary creation of a human being, which would be absent in laboratory creation. It was observed that to create a clone is to sinfully create a human in the image of another human, rather than to have a human begotten in the image of God.

Additional testimony was provided by legal and bioethics scholars. Arguments favoring cloning research focused on the question of whether the harm of cloning was speculative or well established, the recognition of new infertility treatments, and the concept of the inherent goodness of knowledge.

The arguments against human cloning focused on the actual produced clone, rather than the process of cloning. One argument focused on the repugnance many people have expressed about human cloning and the wisdom behind such repugnance. It was suggested that it is sometimes necessary to base moral and ethical action on intuition rather than on rational arguments. Critics also worry that the reasons why a human clone might be desired have been based on a compulsion for biological connectedness, which may place undue emphasis on biology at the expense of the nurturing aspects of human relationships.

More information, including witness lists and transcripts of testimonies, is available on the House Science Committee Web Page, http://www.house.gov/science/welcome.htm, and the NBAC Web Page, http://www.nih.gov/nbac/nbac.htm.

[Prepared by Michele T. Thieman, AAAS Intern]

Health Risks Put Brakes on Xenotransplants in U.S. and Britain

Continuing concern about the infectious disease risks of xenotransplants - animal to human organ transplants - has slowed efforts to commence clinical trials in the U.S. and Britain that would assess the efficacy of such transplants. The British government recently announced a temporary moratorium on xenotransplants following the report of a specially-constituted ethics panel. The panel concluded that no ethical reasons would preclude conducting such experimental transplants, but that clinical trials should await further study of the potential threat of infection by retroviruses and the development of a statutory framework of regulation to protect patients. Until then, a national advisory Xenotransplantation Interim Regulatory Authority has been set up to monitor all related research. The U.S. appeared to be on the fast track last fall when the Food and Drug Administration issued draft guidelines that would permit research on xenotransplants to go forward (see PER, IX (4), Fall 1996). But strong objections raised by those concerned about the risks associated with the use of organs from primates persuaded the FDA to reassess the health risks. No further action on the agency's draft guidelines is expected until additional scientific and public views on the matter are heard at upcoming public workshops convened by FDA and the National Institutes of Health.

Qui Tam Ruling on Plagiarism/Fraud Reversed

A federal appeals court has reversed a lower court ruling that had rewarded $1.6 million to a former graduate student at the University of Alabama who claimed that another graduate student had plagiarized her work and that the University of Alabama had defrauded the government by falsely taking credit for her work in a grant application (see PER, VIII (2), Spring 1995). When the granting agency declined to pursue her claims, the former student filed a qui tam lawsuit under the False Claims Act, which allows citizens to bring suit based on alleged fraud in government contracts. The 1995 district court ruling was reversed in United States ex rel. Berge v. the Board of Trustees of the University of Alabama, et al. (4th Cir. Md), January 22, 1997. The appeals court found that "the evidence is patently clear that there was no plagiarism ... and thus no false statement by" the University of Alabama.

SCIENTIFIC PUBLISHING, ETHICS AND THE LAW

[Last Fall PER received an unsolicited manuscript for publication from Dr. Adil E. Shamoo of the University of Maryland. It described his encounter with a journal that first accepted and then rejected his paper based heavily, but not entirely, on legal advice regarding possible libel. After some independent investigation and subsequent revisions of the manuscript received by PER we decided to publish the paper and invite the publisher and editor-in-chief of the journal to respond. Dr. Shamoo's paper appears immediately below, followed by responses received from Norman Quist and Edmund G. Howe of the Journal of Clinical Ethics. - Ed.]

Attempts At Suppressing Data
Adil E. Shamoo, University of Maryland

My interest in issues of research quality and accountability was sparked in mid-80's by the few scientific misconduct revelations of fraud, fabrication, plagiarism, sloppy work, and conflict of interest. Since then I have organized several international conferences and in 1988 founded and became the Editor-in-Chief of the journal: Accountability in Research. Recently, congressional hearings have revealed not only violations of confidentiality, the bypassing of informed consent and even fraud, but also abuse of human subjects in research. I began my work on these problems with great enthusiasm and naiveté. I truly thought that some of these problems could be resolved swiftly by the scientific community once they were informed about them. It was my belief (and still is) that scientists could resolve a great deal of the problem by opening their laboratory notebooks to all responsible parties. In other words, complete openness of research data could go a long way to alleviating a great deal of public concern. In 1989, I suggested "Data Audits" in order to assure the public that we are open to scrutiny, while also assuring scientists that these audits should not be conducted by the government or universities but by an independent organization. Moreover, I also emphasized the infrequent nature of "audit." To my amazement, to date none of the hundreds of thousands of researchers has offered, volunteered, or accepted the notion that his or her research data be made available to the public or other scholars for scrutiny (after the publication has appeared). More shocking, however, were serious efforts to suppress my report when I was about to publish unpleasant results based on analysis of published research data.

I surveyed three decades of research (41 U.S. studies) conducted by psychiatric researchers on patients with schizophrenia where the patient, as part of the research protocol, underwent a period of washout of the drug (no medication intake for a period of time ranging from two to eight weeks). The washout was then followed by the subjects-enrollment in a research protocol where some received a new drug and some received a placebo. The research protocol ranged from a few days to over a year. Nearly 40% of patients experienced a relapse (return of the symptoms such as psychosis and delusions) during the research protocol. After the washout, some of the patients were kept drug free for over a year despite their relapse.

My interest in psychiatric research began in 1991 through a referral by the National Alliance for the Mentally Ill (NAMI) as their expert on ethics in research, as a result of a family contacting them in reference to their son, who was a subject of such research. After two years of research on the issue, I published a paper in 1993 entitled "Accountability in Research using Persons with Mental Illness."1 Further, I initiated a study of all the literature on washout/relapse experiments conducted between 1967-1992. I was joined in my efforts by a physician at our school. We found that about twenty-three hundred (2309) patients were included in the 41 studies. About 39% (900 patients) suffered relapse and 10.5% (243 patients) dropped out of the research, usually without any follow-up. The informed consent process was described without reporting that any patient was disqualified from entering the program due to

lack of comprehension of the proposed research or the substantial risk of relapse. Furthermore, we found a few experiments where the street drug Amphetamine was used to induce symptoms with so-called "challenge doses" in order to study relapse. A typical statement in the method was "...psychotic patients with schizophrenia [were recruited].... All of the patients in this study were capable of informed consent and entered voluntarily."

In March 1994, I mailed the draft paper to Jay Katz, M.D. a psychiatrist and a leading ethicist on human experimentation, and a professor at Yale Law School for his comments. Dr. Katz responded "...it is in good enough shape to be submitted for publication." We considered several journals for publication. After a brief conversation with the Editor-in-Chief of the *Journal of Clinical Ethics* (*JCE*), we submitted the paper on April 1, 1994 with a copy of Dr. Katz's letter. The original title of the paper was "Intentionally Causing Relapse: Breakdown in Ethics." In June 2, 1994, we received a letter from the managing editor informing us that it "...has been accepted for publication in the *Journal of Clinical Ethics* pending minor revision as suggested by the reviewers." The letter ended with "We look forward to receiving your revised paper." On July 28, 1994, we revised the manuscript, taking all the comments under serious consideration. Soon after that, I had a telephone conversation with the editor of the *JCE*. He informed me that it is customary for the journal to send manuscripts for comments from two pros and two cons. Furthermore, because of the importance he placed on our paper, he was writing an accompanying editorial which, he informed me, would state that the paper would be one of the two most important articles ever published in the journal. On October 21, 1994, the managing editor of *JCE* mailed me the galleys and said the paper "is scheduled to be published in volume 5, number 4." The letter said, "We look forward to seeing your provocative article in the journal." A few days later, we mailed the galleys back with minor corrections.

On early November 1994, I received a telephone call from the Editor-in-Chief of the *JCE* informing me that the press had literally stopped and my paper would not be published. He told me that the decision was made primarily by the publisher in the face of a threat of libel suit received from the attorney of one of the psychiatric researchers whose paper was cited in my article. He refused to tell me the name of the lawyer or the psychiatric researcher. He said the publisher is small, with no liability insurance. He further informed me that several psychiatric researchers had been looking over my article with a fine-tooth comb and had found flaws undermining the paper. I tried to probe further about some of the flaws and concerns, and in a subsequent telephone call that I initiated, I offered to revise the manuscript to be less accusatory in tone and correct any factual errors with an apology to the editor and the researchers for any errors. He said maybe an opinion as to the legitimacy of such discussion from notables such as Jay Katz could be helpful. He was not encouraging that even with such modifications the publisher would publish it, but there remained a chance.

In the meantime, numerous psychiatric researchers had access to our paper beyond those recruited to prepare commentaries. The publisher had requested the views of the commentators on a yet privileged, unpublished manuscript. Unfortunately, some of those commentators copied the manuscript and distributed it to their colleagues in violation of confidentiality. Knowledge of our paper became obvious to me when in conversations with others and at conferences, details were quoted.

We modified the paper extensively, and even changed the title to "Ethical Concerns About Relapse Studies." We also rechecked the data, corrected what few errors there were, and altered the tone of the paper. After these revisions, we then mailed the paper to several colleagues, attorneys (including our university counsel), and Jay Katz for their comments. The thrust of the comments we received were similar to Jay Katz's comment that: "There is nothing in the manuscript that contains anything that is 'libelous'. Clearly, your manuscript contributes to the legitimate debate on these ethical concerns" (December 12, 1995). We considered all the comments and revised the manuscript again, being very careful not to offend the sensibilities of the researchers.

In mid-February 1995, we resubmitted the revised paper to *JCE* again, but this time directly mailing it to the publisher, who would be making the final decision. A month later, the publisher acknowledged receiving our manuscript, noting that it would undergo the "usual" review procedure. After waiting three months from the new date of submission and having received no communication as to its fate, we decided on June 7, 1995 to withdraw the paper from JCE and submit it to the *Cambridge Quarterly of Health Care Ethics*. The editor and the publisher of the *Cambridge Quarterly* were informed fully of the history of the paper. The paper was reviewed and accepted with very minor modifications.2

The psychiatric research community3,4 claims that all recent efforts by the "ethics community" to monitor research with human subjects have had a chilling effect on "freedom of inquiry" and that they play directly into the hands of anti-science advocates. It is quite disconcerting to see these same academic researchers who cherish their freedom of inquiry resort to censorship, intimidation, and suppression of research data based on their own published papers. The public's trust and confidence in the research community at large in the past ten years has eroded,4,5 in large part because of the scientists' continued defiance in the face of increasing demands for accountability. The primary avenue of accountability is openness in discussing all aspects of the problems and in sharing data records. It is unfortunate that neither the scientific community at large nor the psychiatric research community will open its research data records to the public or other scholars for scrutiny that includes peer review/audits when necessary. The few revealed cases and our data on psychiatric research indicate that the research community may, in some cases, have violated the basic tenant of conduct towards human subjects to ensure comprehension, lack of duress and coercion, and provide sufficient knowledge in securing informed consent. The question remains whether such abuses are isolated incidents or part of a more prevalent spectrum of such practices. We will never know the answer to this question unless the research data records are opened to scrutiny.

Endnotes

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2. Shamoo, A.E. and Keay, T. (1996). "Ethical Concerns about Relapse Studies," *Cambridge Quarterly of HealthCare Ethics*, 5:373-386.

3. Carpenter, W.T. (1996). "Schizophrenia Research: A Challenge for Constructive Criticism." In *Ethics in Neurobiological Research with Human Subjects*, Shamoo, A.E., Editor, Gordon and Breach, Buffalo, N.Y. , pp. 217-230.

4. Shamoo, A.E. (1996), Editor. *Ethics in Neurobiological Research with Human Subjects*, Gordon and Breach, Buffalo, N.Y.

5. "Our Responsibilities Toward Persons with Mental Illness as a Human Subjects in Research" (1994) **The Journal of the California Alliance for the Mentally Ill**, 5:14-6.

Responses

Norman Quist, Publisher of *The Journal of Clinical Ethics*

Given the events that surrounded the review of Professor Shamoo's paper, "Intentionally Causing Relapse: A Breakdown in Ethics," for publication in *The Journal of Clinical Ethics*, it is ironic that Professor Shamoo's critique of that process has been entitled "Attempts at Suppressing Data." If this title suggests complicity by *The Journal of Clinical Ethics* in the suppression of data, the association is undeserved; a review of the journal's handling of the paper suggests the opposite.

It was our initial exuberance for Professor Shamoo's research that led us to speed up our process of double-blinded peer-review, in which we usually wait for all of the reviews to arrive before we notify an author regarding acceptance for publication. After receiving some of the reviews, we decided to accept the paper, subject to minor revision, based on the comments we had received. In our enthusiasm to champion Professor Shamoo's work, we did not wait for all of the reviews to be returned before we contacted him. This was clearly a mistake. One later review, especially, identified several serious structural problems; correcting these would have required that Dr. Shamoo conduct additional research and make extensive revisions. What we had anticipated would be minor revisions became much more significant.

When we learned that the paper contained statements that could be grounds for a suit of libel, I asked an attorney versed in this area of law to review the manuscript and report on the merits of a libel claim. I learned that while anyone can threaten to bring a libel action, I was advised that, in the instance of this paper, there were reasonable

grounds for concern. Following this conversation, the manuscript was sent to a second attorney for review. The advice I received was that it would be best for the journal to stand aside and not publish the article. I also learned that even with insurance for libel, the journal would have a contractual obligation not to expose its insurance carrier to the possibility of a libel suit if the journal had been previously advised, by counsel, that there was reason to believe that there was a potential libel problem with the paper.

Certainly it is possible to obtain conflicting opinions on the merits of the legal issues here, and to obtain differing opinions regarding the success of a possible action for libel. In this case, I was advised by two qualified attorneys, who reviewed the paper independently, to refrain from publishing the manuscript in the form in which it was originally submitted. Given this advice, and the highly critical review that this paper subsequently received, as I considered the options, and the possible consequences, I decided to heed the informed advice of counsel. Moreover, as the publisher, I firmly believe that the integrity of the journal depends on our commitment to the principles of responsibility and fairness, as elusive as these principles may sometimes be.

Edmund G. Howe, MD, JD, Editor in Chief of *The Journal of Clinical Ethics*

As the editor in chief to whom Dr. Shamoo refers, I appreciate the opportunity to share a few of my thoughts on the issues he raises and the circumstances he reports. I consider the problems he addresses regarding research involving patients with mental illness, and particularly those with schizophrenia, among the most important in medical ethics. The first problem his study highlights is when – if ever – these patients should be taken off psychotropic medication or have it reduced to determine whether an investigational drug would be of greater benefit. This question is extraordinarily important because whenever these patients become ill – as a result of their medication being withdrawn or of its not being effective – their suffering is greater, and substantially greater, than that of most other patients. The second problem highlighted is the need to find the best way to obtain these patients' informed consent. This question is critical, because it is the patients' capacity for self-determination that is affected by their illnesses.

Regarding the process by which we decided not to publish this article in *The Journal of Clinical Ethics*, I wish to add to the discussion two significant considerations. First, the four persons who principally were involved struggled at great length with the moral concerns at stake, and, in my opinion, showed the highest integrity and conscientiousness in making their ultimate decision, though their deliberations differed widely. As the basis for this statement is not self-evident, I must be specific: the staff of *JCE* struggled continuously over the competing ethical considerations before giving priority to what we thought we owed our readers and the greater community of patients and careproviders – namely, to keep the journal existing.

The second consideration is the conduct of those involved. The researchers whose work Dr. Shamoo examined were themselves committed to providing patients with a better life, and each believed that they acted according to the highest ethical standard in seeking informed consent – we learned this from an author who wrote a commentary on Dr. Shamoo's article, who called each researcher in preparing his article. The lawyer who indicated that *JCE* could expect to be sued if it published Dr. Shamoo's article is known for taking repeated initiatives on behalf of patients to protect their rights, and is among a handful of attorneys who have worked actively on behalf of these patients. Finally, Dr. Shamoo's efforts on behalf of these patients, and particularly his writing this article, are courageous and tireless, and represent the epitome of humanitarian concern and self-sacrifice on behalf of others who are less empowered; a standard to which we should all aspire.

How can it be that all of these persons are praiseworthy? To answer this question, I must state an ethical reality that is all too often overlooked. That is, any policy, even one that is ideal, must occasionally effect outcomes that are unfortunate. In this instance, the "causative" policy is our system of law, which allows persons under certain circumstances to sue and to threaten to sue when this would further their best interest. *JCE* and any journal within this system can obtain insurance against suit for libel. Even then, if a journal had reason to know in advance that a publication was libelous, the insurer may withdraw the coverage. A journal then may have to decide, as *JCE* did, what end, if any, warrants sacrificing its own survival.

The alternative is to change the law. While many might argue in favor of this, I am not so sure – the result might be worse than is easily imagined.

RESOURCES

In Print

Your Genes, Your Choices describes the Human Genome Project, the science behind it, and the ethical, legal, and social implications of the project. Written as part of the Science + Literacy for Health project of the American Association for the Advancement of Science (AAAS) and funded by the Department of Energy, this book discusses the issues we all face in the light of genetic research and technologies. Using fictional case studies, *Your Genes, Your Choices* provokes readers to consider such questions as: Should you take a genetic test to find out if you inherited a fatal disease? Should you give a sample to police for DNA screening to clear your name prove your innocence in a murder case? Should you drink milk from cows injected with growth hormone? *Your Genes, Your Choices* does not answer these questions for the reader, but instead provides the pros and cons of the issues while teaching the basic science behind genetics. There is also a seven-minute video intended to stimulate group discussion. *Your Genes, Your Choices* is available now for free ($5 postage and handling), along with accompanying video. To order, contact Maria Sosa, AAAS, 1200 New York Avenue, NW, Washington, DC, 20005; (202) 326-6454; WWW http://ehr.aaas.org/ehr.

ANNOUNCEMENTS

The Societal Dimensions of Engineering, Science, and Technology (SDEST) program folds together two former NSF programs, Ethics and Values Studies, and Research on Science and Technology, in the Division of Social, Behavioral and Economic Research of the National Science Foundation. The Ethics and Values Studies (EVS) component focuses on developing and transmitting knowledge about ethical and value dimensions associated with the conduct and impacts of science, engineering, and technology. The Research on Science and Technology (RST) component supports research to improve approaches and information for decision making concerning management and direction of research, science and technology. In Ethics and Values Studies (EVS), projects might address such issues as: scientific or professional ethics, including research ethics; the role of social or organizational values in scientific or engineering practice; equity issues in the development, use and effects of science or technology; and normative issues in decisions involving science or technology. In Research on Science and Technology (RST), projects could address such topics as: factors influencing the directions and impacts of scientific and engineering research and technological change, both domestic and international; issues of human resources in science and technology; and the relationships between individual, organizational and political adaptation or change and scientific and technological innovation or change. Target dates for proposals are February 1 and August 1; proposals on undergraduate education should be submitted for the February closing date of the program, since their review will be coordinated with that in the Division of Undergraduate Education in the Directorate for Education and Human Resources. Preliminary proposals, giving a description of the project and its suitability for consideration in SDEST, can be submitted at any time. For further information, contact Program Directors Rachelle Hollander or John Perhonis, NSF, Room 995, 4201 Wilson Blvd., Arlington, VA, 22230; (703) 306-1743; Fax (703) 306-0485; E-mail rholland@nsf.gov or jperhoni@nsf.gov; http://www.nsf.gov/nsf/nsfpubs/nsf9728.htm.

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On June 25-28, 1997, the Indiana University-Bloomington is sponsoring the **Fourth Annual "Teaching Research Ethics" Workshop**. The cornerstone of the project is an intensive workshop, which helps science faculty members to use existing materials to train their students in research ethics and to develop effective methods and materials of their own. Registration is required and must be paid by May 2, 1997. For more information and a registration form, contact Kenneth D. Pimple, Ph.D., Poynter Center, Indiana University, 410 North Park Avenue, Bloomington, IN, 47405; (812) 855-0261; Fax 855-3315; E-mail pimple@indiana.edu; WWW www.indiana.edu/~poynter/index.html.