Human Subject Regulations: Whom Are We Protecting From What, and Why? Working to Align Incentives with Ethical Goals

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C. K. Gunsalus was the lead organizer of the conference on which this article is based.

There is considerable concern in professional societies and universities, especially in the behavioral and social sciences, over the problems surfacing in the application of human subject protection policies outside the biomedical arena. A working conference hosted by the University of Illinois Center for Advanced Study in April 2003 gathered a diverse group of scholars, federal officials, and representatives from disciplinary societies to share perspectives and information, and to discuss possible solutions to the dilemmas this is creating for university-based scholars whose work involves interactions with people. A paper in PER last year by Joan Sieber, Stuart Plattner and Philip Rubin provided a compelling description of the problems surfacing as Institutional Review Boards (IRBs), their administrators and other university officials respond to a changing regulatory environment. Across the country, in a wide range of disciplines, there are increasing instances of hyperzealous interpretations of the regulations, including my favorite of the examples cited by Sieber, et. al., in which “A linguist seeking to study language development in a pre-literate tribe was instructed to have them read and sign a consent form.”

The “mission creep” seen in IRBs across the country is stimulated by highly publicized university-wide research “shut downs” by federal regulators and the goal of limiting institutional liability, combined with sincere desire to assure protection of human subjects of research. The result, however well meaning, appears to have had a disproportionate effect upon research involving low-risk, low-harm methodologies in the social sciences and behavioral research.

Unfortunately, more is at risk than misapplication of scarce resources: research in these areas is being delayed, sometimes forbidden or, perhaps more commonly, abandoned as word spreads about the difficulties of securing timely approval from local IRBs. Writing in Academe, Margaret Blanchard, the William Rand Keenan, Jr. Professor of Journalism and Mass Communication at UNC Chapel Hill, wrote of a faculty member in her department who used to give assignments involving current topics relevant to the lives of his students but, in light of IRB interactions, “says he now limits his class projects to ‘bland topics and archived records.’”

As mission creep has led IRBs to regulate fields totally unanticipated by the original drafters of the Common Rule, the federal regulation governing research using human subjects, questions of academic freedom and of the First Amendment rights of researchers have begun to arise.

Although these topics have been gaining increasing attention, the Illinois Conference was the first targeted gathering of scholars and policy officials across a broad range of fields. Disciplines of those attending included anthropology, English, business, psychology, history, journalism, organizational behavior, law, ethnography, social work, philosophy, communications, sociology, and medicine. Federal officials from the National Science Foundation, Department of Education, and the Office of Human Research Protection attended.

The Illinois Conference focused on two sets of questions, the first definitional:

- What is research? (Or, what is not research with human subjects as covered by the Common Rule?)
- What is risk? What is harm?
- What is a human subject?

Second, we asked, more fundamentally perhaps:

- Who are we protecting?
- From what?
- Why?
- And at what cost?

As these questions were examined, three distinct sources of the problems seen in non-biomedical research emerged at the conference: first, there are too many incentives in our present regulatory system for universities and their IRBs to focus on documentation of technical compliance (forms signed and properly filed) at the expense of substantive protections for human subjects. As Robert J. Levine stressed, “consent is a process, not an event.” This conflation of technical compliance with substantive ethical review is a significant complicating factor. Is there another way for a “good” IRB to demonstrate that it is meeting its obligations than to be able to document that all its signatures are in the right places? Some

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“minimal risk” is an area in which vastly better guidance must be provided when applied to research that does not involve physical discomfort or harm.

Finally, some forms of scholarship simply do not fit a regulatory model that derives from and focuses upon the protection of human subjects in biomedical research. Journalism, for example, puts a higher value on the public’s right to know than on the protection of the reputation of an individual who has been the subject of an investigative report, such as the proverbial crooked alderman. As put by Ivor Pritchard of the Department of Education at the conference, “an ethical journalist may responsibly “get” the subject of his or her story. An ethical psychologist may not.”

The stakes are high. In order to function soundly, compliance systems require acceptance and at least minimal respect from those who are regulated. Actions by IRBs that do not make sense to scholars and researchers in entire fields will impair (as they already may) the credibility of IRBs.

It became clear at the conference that the IRB community needs to hear and to respond to the accumulating concerns of researchers in non-biomedical fields and to listen non-defensively. No doubt, there are some uninformed, confused, inexperienced, and/or recalcitrant investigators who resent any oversight of their work. However, there is also significant evidence of very real problems even with “good” IRBs. Defensive attitudes that dismiss all concerns as unfounded, ignorant, misplaced, etc., do not help to protect human subjects of research. Substantive, thoughtful responses will.

Solutions proposed at the Illinois Conference include developing and disseminating better guidance on the application of existing definitions in the Common Rule, collecting and disseminating “best practices” on procedural matters, preparing information and drafting guidance for federal regulators and legislators as regulations and federal statutes are revised. For example, Robert Levine’s keynote speech,

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The Illinois Conference White Paper (under development) will also address how to differentiate research involving human subjects that is and is not covered. Many activities that involve “interactions” with humans are nonetheless not “covered research” involving human subjects and we need better to understand the difference. Responses to the panels elucidating federal policy and suggesting constructive directions by Ivor Pritchard of the Department of Education and Phillip Rubin of the National Science Foundation were helpful in sharpening the questions our community must resolve and that will be addressed in the White Paper.

In addition to developing better guidance on the meaning and coverage of present regulations, much improvement can be gained by disseminating procedural best practices. For example, one significant source of concern in many disciplines is the lack of appeal from IRB decisions applying the regulations to proposed activities. In fact, federal regulations—and many institutional policies—permit an appeal mechanism, but this is not widely known or understood nor is it clear how effective these appeal mechanisms are. Working with federal regulatory agencies, information on this and other aspects of how IRBs operate in practice is needed.

Relatvely, the Illinois White Paper will also describe various models for distributed responsibility that may assist both in reducing the burden on overworked IRBs.
(Regulations continued from page 2) and improving the quality of resulting oversight. There are many successfully operating models of oversight that provide accountability and meaningful protection for human subjects but do not require all scholarly activities to go through a central IRB.

Finally, the White Paper will examine the regulatory structure and explore possibilities for a more nuanced system of oversight. At the conference, participants debated whether there are potentially different levels of risk for research involving human subjects that would warrant different levels of review: 1) the current system requiring advance review and approval before certain activities (such as those involving more than minimal risk) may be undertaken; 2) a system providing for post-hoc complaints (perhaps applicable for endeavors such as oral history projects); and, 3) activities for which the recourse for addressing problems would be the legal system.

It does not detract from our broadly shared commitment to the ethical treatment and protection of human subjects of research to observe that our regulatory system is in need of improvements. There are many good ideas in circulation. The work of the Illinois Conference will be extended and joined with the efforts of others working toward such improvements.

1 More information about the conference, and the positions papers submitted for it, can be found at: http://www.law.uiuc.edu/conferences/humansubject/index.asp
2 Sieber, Joan E., Plattner, Stuart and Rubin, Philip. “How (Not) to Regulate Social and Behavioral Research.” Professional Ethics Report, Volume XV, Number 2, Spring 2002, pp. 2-4
3 Ibid, p1.
9 Representatives of the Centers for Disease Control were invited and accepted, but were unable to attend due to other pressing matters; epidemiological work can raise some of the same issues examined at the conference.

IN THE NEWS

CONTAMINATED TISSUE IMPLANTS BLAMED ON FDA DELAYS

The FDA announced ambitious plans in 1997 to regulate the human tissue industry, but Members of Congress chided the FDA for failing to make any progress in regulating the industry.

The American Association of Tissue Banks, an industry group that represents about half the tissue banks in the United States, supports many of the proposed regulations, but other groups, including surgeons, claim that the regulations would increase costs and reduce supply without increasing safety. Included in the listed items provided by tissue banks are human eye tissue, heart tissue and donated tendons and cartilage. All of these tissues are used in surgical procedures; tissue banks also provide tissues used for skin grafts for burn patients.

A staff report from the Senate Committee on Governmental Affairs found that only a few states regulate the tissue industry, and any safety precautions created by the government are currently nonbinding. The CDC has received reports of approximately 62 infections associated with human tissue transplants since 2001, and there has been one reported death. *JF

FDA WARNS UNIVERSITIES OVER STUDIES INVOLVING TRANSGENIC ANIMALS

The FDA is concerned about the human consumption of transgenic animals such as cows, sheep, and pigs. In May, the FDA sent letters to 70 land-grant institutions and universities conducting agricultural research to remind them of FDA regulations on the use of transgenic animals. This action is a result of the discovery that the University of Illinois, Urbana-Champaign (UIUC) sold 386 pigs associated with research studies to a livestock dealer. The animals eventually ended up in a slaughterhouse for human consumption. The pigs were the offspring of transgenic and normal pigs. UIUC researchers had inserted genes into pigs to increase milk production and allow the offspring to digest the milk better and grow faster without the use of drugs. Each pig was tested prior to the sale to ensure that it did not carry the transgene. Originally the FDA accused UIUC of failing to document whether animals associated with bioengineered research had entered the human food supply, but UIUC is working with the FDA to verify that the pigs were free of the transgene. Both organizations now agree that the problem was a result of bad communication rather than wrongdoing.

Initially, the agency regulated only transgenic animals intended for human consumption. Now it has expanded the regulation to include the research of transgenic animals in pharmaceutical factories or models of human disease. The FDA claims jurisdiction to regulate the use of transgenic animals based on the premise that genetic material inserted into the animals is equivalent to an experimental drug. Universities may need to file an application with the agency before conducting transgenic studies. The FDA letter sent to various universities did not clarify the agency’s regulations but asked researchers to contact the FDA for further guidance. The FDA is planning an educational campaign to make sure university researchers are aware of the regulations.

*JF

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(News continued from page 3)
The FDA wants to be consulted in advance and in writing about the disposal of normal and engineered animals. John Matheson, an FDA toxicologist, says that the FDA has received requests from various universities to approve the sale for consumption the normal offspring of bioengineered animals. The FDA will also be conducting onsite investigations to ensure that research records on transgenic animals are correctly maintained.

At this time, the FDA has given universities little guidance in this area. Gregory Jaffe, director of the biotechnology project at the Center for Science in the Public Interest, states that the lack of guidance might be because the FDA usually deals with industry, not universities. On the other hand, many universities don’t necessarily know that their research requires FDA regulation. Bill Murphy, associate chancellor for public affairs at UIUC, states that, while the procedures necessary to ensure understanding of and compliance with the regulations may take a little time to work out, as long as both sides act in good faith, there will be no problem.

For additional information see the following:
FDA Center for Veterinary Medicine website:
http://www.fda.gov/cvm/biotechnology/bio_drugs.html
Investigational new animal drug (INAD) regulations within 21 CFR 511.1(b): http://www.access.gpo.gov/nara/cfr/waisidx_02/21cfr511_02.html *MF

HHS PROPOSES NEW GUIDANCE FOR FINANCIAL CONFLICTS OF INTEREST IN HUMAN SUBJECTS RESEARCH
On March 28, the Department of Health and Human Services Secretary proposed a draft guidance for protecting human research subjects from being harmed by financial conflicts of interest in research. The draft guidance, “Financial Relationships and Interests in Research Involving Human Subjects: Guidance for Humanitarian Review Boards (IRBs), research facilities, and other entities reviewing and Subject Protection,” was published in the March 31 Federal Register and is directed towards investigators, Institutional Review Boards, research facilities, and other entities reviewing and implementing research proposals in the HHS and its agencies.

The proposed guidelines, consisting of questions and “points to consider,” are intended to provide a “clearer framework for identifying and managing potential conflicts of interests as early as possible.” The guidance is intended to aid users in assessing whether financial interests interfere with the rights and welfare of test subjects and suggests possible actions to address or resolve any conflicts of interests that may exist. Recommendations in the guidance include suggestions to separate financial from research decision-making, establishing committees to review projects for financial interests in research, directly informing test subjects of project funding sources, and arranging for an independent third party to inform subjects and obtain consent from them.

The March 31 Federal Register can be viewed at: http://ohrp.osophs.dhhs.gov/references/fr03-7691.pdf *JC

HOUSE MEMBERS ASK PRESIDENT TO EXPAND POLICY ON STEM CELL RESEARCH
On May 15, 2003, eleven Members of the U.S. House of Representatives wrote President Bush expressing their concern over the President’s policy on stem cell research. The Members, all Republicans, noted that the stem cell lines available for federally-funded scientists under President Bush’s August 9, 2001 policy were grown using mouse feeder cells, which could contain infectious agents that may cause disease in humans. Researchers at Johns Hopkins University have produced uncontaminated stem cell lines not covered under the President’s current stem cell policy. The letter asks the President to consider whether changes should be made to the policy to include the lines produced by Johns Hopkins. *JF

ISRAEL CONSIDERS WHETHER PARENTS SHOULD BE ABLE TO CHOOSE THE SEX OF THEIR CHILDREN
In rare cases there are accepted reasons for selecting the sex of one’s child. In Israel, parents with serious sex-linked genetic diseases use pre-implantation genetic diagnosis (PGD). PGD entails the creation of embryos by in vitro fertilization, analysis of cells for sex determination and genetic disease, and then implantation of an embryo into the mother. Many ethical dilemmas arise related to the use of this technology. Does a couple have the right to choose the sex of their child simply based on preference? What if there is no known genetic risk? What if the couple can conceive naturally? Should only IVF couples be allowed to choose the sex of their child?

Experts gathered at the Jerusalem Center for Ethics at Mishkenot Sha’ananim to present their views on whether the medical community should allow non-medically related sex selection. Various risks to sex selection were discussed. Dr. Carmel Shalev, head of the medical ethics unit at the Gertner Institute at Tel Hashomer, argued that the practice should be barred because more male children will be selected resulting in a shortage of females. This could result in men stealing or buying wives in geographic areas that are gender imbalanced. Professor David Hed of the Hebrew University’s philosophy department, countered that throughout history there have been times when there was a gender imbalance and we have managed to persevere until balance was restored. In addition, countries like India perform PGD legally based on discrimination against women, not based on sex selection.

Others worry about the unnecessary medical procedures that women will go through in order to choose a boy or girl. Women could risk medical complications due to the procedure, and the success rate of approximately 20% is low. Some religions stress the natural method of procreation, contending that tampering with nature in order to conceive and then using technology to allow sex selection is (News continued on page 5)
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not natural. Rabbi Dr. Mordechai Halperin, the Health Ministry’s medical ethics advisor, states that couples undergoing IVF for fertility reasons should be able to choose the sex of their child, but couples should not undergo IVF treatments for the sole purpose of sex selection. *MF

OHRP GUIDANCE ON THE INVOLVEMENT OF PRISONERS IN RESEARCH
On May 23, 2003, the Office for Human Research Protections (OHRP) provided additional regulations1 for the protection of prisoners as human subjects participating in biomedical or behavioral research conducted or supported by the Department of Health and Human Services (HHS). The new regulations address the fact that prisoners need additional safeguards because of the stress of making voluntary and educated decisions regarding participation as human subjects.

Institutional Review Boards (IRBs) review protocols involving prisoners as subjects and the research must now meet additional requirements. The new research requirements include elements such as: the risks must not be greater than risks that would be accepted by non-prisoner volunteers; control subjects must also be selected from among the prisoners; and participating in the research studies will have no effect on the parole chances of the prisoner. If the prisoners may not benefit from the research, then a consultation with experts, such as experts in penology, medicine and ethics, is also required before the research project can begin.

The new regulations also address the issue of a participant in a medical study becoming a prisoner during the study. In this instance, the IRB will review the protocol of the study and determine whether the subject can continue in the protocol of the study and determine if the prisoner is to be allowed to participate. In some cases, the IRB will review the prisoner’s parole and the case of the study to determine if the prisoner can continue in the study. The new regulations also address the issue of prisoners as human subjects participating in biomedical or behavioral research conducted or supported by the Department of Health and Human Services (HHS). The new regulations address the fact that prisoners need additional safeguards because of the stress of making voluntary and educated decisions regarding participation as human subjects.

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STATEMENT BY THE EUROPEAN GROUP ON ETHICS IN SCIENCE AND NEW TECHNOLOGIES ON ADVERTISING GENETIC TESTS VIA THE INTERNET
The European Group on Ethics in Science and New Technologies issued a statement on February 24 to “alert civil society and decision-makers on problems raised by advertising genetic tests via the Internet.”

The Group cited social, legal, and ethical concerns regarding Internet-based advertising of genetic tests for paternity and predisposition to genetic diseases due to potential ramifications of the tests. Some tests were deemed by the Group “misleading and incomplete” in nature because of the limited predictability of multigenic diseases. The statement also raised concerns about data collection for the tests and possible non-compliance with consent regulations, particularly in the case of paternity testing.

Prior documents issued by the Group and the Council of Europe’s Convention on Human Rights and Biomedicine deemed “appropriate genetic counseling” an integral part of genetic testing, but Internet-offered tests neglect to consider the harmful effects of testing without proper advice and counseling. The Group’s statement voices concerns about discrimination with test results and the violation of rights, including that of equality and confidentiality of health care information. Furthermore, the Group believes that advertising a genetic test commercializes the tests and increases demand for testing that may disrupt “social and personal conflicts.”


IN THE SOCIETIES
PROTECTING THE PUBLIC AND THE ENVIRONMENT: A RESPONSIBILITY OF CANADIAN PROFESSIONAL ENGINEERS
A Report by the Canadian Academy of Engineering
Ottawa, February 2002

Engineers have the responsibility to ensure that their contributions provide special attention to the protection of the health, safety, and well being of the public and the environment. To meet this goal, a professional engineer must be competent and act ethically and accept responsibility in order to ensure that the public’s welfare is protected in areas where the public may be lacking the competence and judgment. This report by the Canadian Academy of Engineering addresses the question: “is the legislation and practice of professional engineering in Canada adequate to provide the public with the protection that it needs and deserves?”

The Canadian Academy of Engineering has developed several recommendations for the ethical practice of engineering. The Academy recommended that a standard legal definition that specifically addresses professional responsibility be universally accepted, including when the engineer’s work is not directly for a public client because public welfare can be negatively affected regardless of the contracting parties. Because the potential for success or failure occurs at the design stage, one effective protection is to require engineers to identify potential problems with their designs and to take responsibility in the event that a problem occurs. The report recommends that the Canadian Council of Professional Engineers (CCPE) definition of professional engineering be amended to read:

“The practice of professional engineering means providing and accepting responsibility for any act of planning, designing, composing, evaluating, advising, reporting, directing or supervising, or managing any of the foregoing that requires the application of engineering principles, and that concerns the safeguarding of life, health, property, eco-

(Societies continued on page 6)
**Societies** continued from page 5) nomic interests, the public welfare or the environment.”

The report also recommends that for all work related to health and safety, the associations should ensure that specific responsibility is designated to “an echelon of professional engineers having appropriate competence.” Due to the complicated nature of engineering projects, one person cannot possibly have all of the expertise necessary, and one chief engineer should not be responsible for an entire project. For example, in many projects there may be a need for a software expert. The Academy believes that engineers should take voluntary personal responsibility on behalf of the public for predicting the impact of their engineering activities and informing their employers of potential risks. Employment contracts should have a provision specifying the engineer’s responsibility to the public, and associations should provide a method of dealing with conflicts arising between engineers and employers. This policy will assist engineering companies with legal defense, public image and public relations.

For further information regarding this report see www.acad-eng-gen.ca *MF

**AMERICAN NUCLEAR SOCIETY APPROVES NEW CODE OF ETHICS**

The American Nuclear Society’s (ANS) Board of Directors approved a code of ethics and professional conduct based on the Society’s mission of “improving the understanding of nuclear science and technology” on June 5. The code of ethics vowed that members would “uphold and advance the integrity and honor of their profession” for the “enhancement of human welfare and the environment.” The code of ethics listed twelve practices of professional conduct, including practices to disclose information if “duties might have adverse consequences for the present or future,” to act with the safety of others and the environment in mind, and to take full responsibility for one’s actions. The code of ethics was approved by the ANS Special Committee on Ethics in November 2002.

The American Nuclear Society’s webpage can be found at http://www.ans.org.

The code of ethics can be viewed at http://www.ans.org/about/coe. *JC

**RESOURCES**

**THE ANATHEMA OF GM FOOD AND DEVELOPING COUNTRIES**

*by Kevin Alleman*

It’s widely known that the United States and Europe express divergent attitudes toward genetically modified (GM) crops. We in the US have long accepted a market-driven food culture, which is shaped in part by advances in GM technology. Europeans, on the other hand, are more reluctant to accept the integration of global market pressures on their culinary heritage; in part, due to concerns with the application of bioengineered crops on public health and safety, food security, and environmental integrity. Much of the consternation has risen to a level where some countries have called for prohibitions on the importation of GM food and a cessation of all GM research and farming.

In 1999, the Nuffield Council on Bioethics, an independent think tank in the United Kingdom that examines ethical issues in medicine and biology, took to task examining these issues and released a report, *Genetically modified crops: ethical and social issues*. One of the recommendations concluded that, if the application of GM technology can reduce malnutrition in developing countries, there was a compelling moral imperative “for making GM crops readily and economically available to developing countries who want them…”

With recent developments in GM technology and the persistent mistrust in its application to food development in the UK, parts of Europe and other countries, the Council on 10 June 2003 released a follow-up draft paper entitled, *Discussion Paper: The use of genetically modified crops in developing countries*, to assess the risks and benefits associated with GM crops in developing countries.

One of the key positions in the draft is a recognition that GM technology can increase the yields of crops, but that the benefits and risks must be assessed on a case-by-case basis. This precautionary rule is shielded by the lack of evidence to the Council showing GM crops as causing harm, as advocated by those who seek moratoria on GM research and field trials. The Council has upheld the moral obligation to explore the potential benefits associated with GM crops responsibly in order to reduce malnutrition and poverty in developing nations. And to assuage fears that small-scale farmers would be neglected, since most GM research serves the interests of large-scale farmers in developed countries, a recommendation is made that “additional resources be committed by governments, the European Commission and others, to fund a major expansion of public GM related research into tropical and subtropical staple foods, suitable for the needs of small-scale farmers.”

Another key finding concerns the impact of European Union (EU) policy on regulation and trade. It is recommended that the EU, the Department for International Development, and nongovernmental organizations that monitor agricultural policy for developing nations ought to monitor EU regulatory policies of GM crops because of the lack of infrastructure in developing countries to trace and label GM food. In the fight to reduce malnutrition, the Council finds that it is essential to continue empirically based research in order to determine if micronutrient-enriched GM crops like Golden Rice, which is modified to produce Beta-carotene that the body converts into vitamin A, is in fact effective. This approach, however, is to be offered concurrently with alternative methods of improving needed dietary micronutrients.

A further key finding administers to the donation of emergency food aid by industrialized nations. It is recommended that a choice be offered, whenever possible, between GM and non-GM food when donating emergency food aid, and that full disclosure of what percentage of the food was geneticaly modified is necessary. The recommendation is a

(Resources continued on page 7)
The obvious ethical question that arises is whether it is always “good” to utilize a technology that makes a person feel complete, fulfilled, or “better than well.” In the most extreme example of the made paradox this question can produce, people with apotemnophilia, or the desire to be an amputee, only feel as if they are their “true” or authentic selves once they have a limb (or two) removed. Is healthy limb amputation an enhancing technology, one that is improving the individual’s well-being, or is it just playing into a psychopathology?

Before one gets the impression that this is a book whose primary focus is the bizarre, please note that nothing could be further from the truth. Elliott focuses on enhancement technologies that are fully familiar to anyone who has considered the issue: steroid use, anxiolytic drugs, selective serotonin reuptake inhibitors, cosmetic surgical procedures, and Ritalin, among others. To the extent that the discussion leads to technologies that are not intuitive, or are even shocking, this seems the result of two deliberate, and informative, choices in the book. The first is that Elliott chooses to use the common philosophical method of trying to determine a rule or principle relevant to the discussion at hand, then to examine whether such a rule works in an extreme case, such as that of the apotemnophilic. If the rule or principle breaks down, this tells you something about the rule and about its assumptions.

The second choice is to cast a deliberately wide net in considering what is an “enhancement technology.” The apparent operative definition Elliott uses is a minimal one, encompassing drugs and procedures which alter or “improve” existing human capabilities or characteristics. One benefit of this choice is that some technologies are included that typically haven’t been much discussed in the context of enhancement technologies, such as computer speech synthesis, accent reduction training, and endoscopic thoracic sympathectomy, a surgery that can relieve chronic blushing. As with the more extreme examples, these technologies also challenge assumptions about what constitutes an “enhancement,” and about whether a common set of rules or principles regarding enhancement technologies are discernable. A potential drawback of this approach is that Elliott only briefly addresses some of the core definitional questions of what should be considered an “enhancement technology,” and thus some of the more subtle aspects of this question are lost.

The book as a whole takes a broad look at the questions posed by enhancement technologies and their potential uses, and places the inquiry in the larger framework of questioning the nature of identity. Elliott provides a new perspective for those who have already been considering the impacts of enhancement technologies, and a remarkable introduction for those to whom the subject is new.


1 See, for example, “Utopia, Dystopia, or Just the Next Step?”, PER, Volume XV, Number 2, Spring 2002, for a review of books by Francis Fukuyama and Gregory Stock that examine enhancement technologies.

2 One that could be either a strength or a weakness depending, in part, on the reader’s background in the issues.

3 An excellent discussion on the difficulty of defining “enhancement technologies,” and of the distinctions between enhancement and treatment, is in a book edited by Erik Parens, entitled Enhancing Human Traits: Ethical and Social Implications (Georgetown University Press, 1998). Elliott refers to this work in his notes, and his declining to explore the issues more fully may simply be a recognition that this is a topic which requires a book-length treatment to address fully. That said, it would have been helpful to general readers to address the definitional issues more directly and in more detail than Better Than Well ultimately does.

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**ANNOUNCEMENTS**

Conference — The Center for Science in the Public Interest is holding a conference on Conflicted Science: Corporate Influence on Scientific Research and Science-Based Policy on July 11, 2003 in Washington, DC. More information is available at [http://www.cspinet.org/integrity/conflictedscience_conf.html](http://www.cspinet.org/integrity/conflictedscience_conf.html).

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Conference — The International Dental Ethics and Law Society (IDEALS) and Creighton University School of Dentistry and Center for Health Policy and Ethics are sponsoring the Fifth International Congress on Dental Law and Ethics, from July 31-August 3, 2003 in Omaha, Nebraska. The theme of this year’s congress is “Rights, Access, and Justice in Oral Health Care.” More information and registration is available at http://www.ideals.ac/congress2003/.

Call for Papers — ETHICOMP 2004 will be held April 14-16, 2004 at the University of the Aegean in Syros, Greece. The focus of the conference will be “Challenges for the Citizen of the Information Society.” Abstracts are due September 10, 2003. For more information, visit http://www.ccsr.cse.dmu.ac.uk/conferences/ethicomp2004/.

Conference — The International Observatory on Bioethical and Biomedical Law is holding an International Forum on Bioethical and Biomedical Law on September 16-19, 2003 in Marseilles, France. The theme is “Procreation and Child Rights.” For further information, visit http://www.bio-pharo.com.

Conference — On September 25-26, 2003 in the International Labour Office, Geneva, the Conscience Clause Project will hold an international conference on the legal protection of the individual responsibility of scientists and engineers. For more information, including registration, visit the Association for the Promotion of Scientific Accountable Behavior (APSAB), http://www.apsab.span.ch/clc.

Retreat — The Council of Science Editors and Office of Research Integrity are co-sponsoring a retreat entitled “The Journal’s Role in Scientific Misconduct” on November 7-9, 2003 in Leesburg, Virginia. More information and registration are available at http://www.councilscienceeditors.org/events_03Program_scientific_misconduct.shtml.

Funding — The Office of Research Integrity is accepting grant applications on research topics associated with research integrity in a variety of disciplines. Funding has been increased to $250,000 over three years. The application deadline is November 14, 2003. For more information, visit http://grants1.nih.gov/grants/guide/rfa-files/RFA-NS-04-001.html.