

# Professional Ethics Report

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## Best Statistical Practices to Promote Research Integrity

By John S. Gardenier

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***“The statistician’s role in a biomedical research project is to drive the p-value below 0.05”***

Generally accepted practice? Research misconduct? Both?

### The Concept of Research Misconduct

Over the 20<sup>th</sup> century, there developed an expanding notion of things that are unacceptable in science. Deliberate hoaxes were seen as moral failures early in the century, but differential treatment of human subjects of research based on race, ethnicity, or intelligence were often accepted. The Nuremberg Trials and the Helsinki Universal Declaration on Human Rights contributed to a sea change.<sup>1</sup> That change continues in the evolution of Institutional Review Board (IRB) practices. Separately, a concept of definable “research misconduct” developed late in the century.<sup>2</sup> It was, arguably, limited to \*fabrication or \*falsification of data plus \*plagiarism of exact wording without permission or attribution. These asterisked items are collectively known as FF&P. Some dissenters argued that mere FF&P leaves ample room for malfeasance. In 2000, a common federal definition emerged to include broadened concepts of FF&P plus whistleblower protection.<sup>3</sup>

### “It Will Not Work.”

At a Town Meeting on the then-proposed definition of research misconduct held at The National Academies on November 17, 1999, all scheduled speakers praised the definition as a virtually optimal solution to any remaining problems of research integrity. Some scientists in the audience, especially those from biomedical research disciplines, found it excessively harsh with regard to inclusion of matters of omission, protection of whistleblowers and standards of proof.<sup>4</sup> Others felt it was insufficient. I noted that it did not clearly prohibit deliberate misuse of statistical methods to present false results. When I quoted the aphorism on p-values (above), the reaction of that auditorium full of distinguished scientists was to laugh, despite the clear contempt for statistical honesty. This is dangerous because misuse of statistical methods can be harder to detect than falsification of data and thus be more tempting and less risky to the perpetrator.<sup>5</sup> If caught, one can always claim “honest error” due to a mistaken understanding of the statistical methods. (Institute of Medicine (IOM) member, John C. Bailar III, has long deplored the varying effects of bad statistics on biomedical research; personal discussions with him over several years have greatly influenced my own thinking.)

C. K. Gunsalus, a member of the Ryan Commission that recommended a greatly revised concept of research misconduct<sup>6</sup>— and an

experienced official of the University of Illinois — explained why she felt the research misconduct definition “will not work.” In her experience, institutional colleagues are generally reluctant to brand any actions as “research misconduct” even when they are recognized as immoral, disgusting and scientifically wrong. Absent a finding of “research misconduct,” any deficient scientific practice such as incompetence, sloppiness, misleading reporting or abuse of colleagues may be excused as “honest error” or acceptable academic conduct. We need a more robust concept of responsible conduct in scientific research than the dichotomy between a finding of research misconduct and a presumption of total innocence.

Such a concept is entirely compatible with the IOM’s 2002 report, *Integrity in Scientific Research: Creating an Environment That Promotes Responsible Conduct*. Among other conclusions, that report finds that “No established measures for assessing integrity in the research environment exist.”<sup>7</sup> The proposal herein seeks to address those aspects of an environment that seek to avoid misuses of statistics and to promote best statistical practices.

### A Taxonomy of Statistical Practices in Science

As noted by Sigma Xi in 1997,<sup>8</sup> “No scientist can avoid the use of such [statistical] techniques, and all scientists have an obligation to be aware of the limitations of the techniques they use, just as they are expected to know how to protect samples from contamination or to recognize inadequacies in their equipment.”

This taxonomy is anchored at the high end by the concept of “best statistical practices” and at the low end by the common federal definition of “research misconduct.” Best statistical practices are easy to define, at least in concept. They involve professional expertise in statistical theory, methods and ethics as well as in the subject matter specialties of the research at hand. (Not all such expertise need reside in one person, of course.) In addition, researchers or research teams must apply themselves with diligence to assure: a thorough understanding of the research issue(s) and prior results, the relevant data, relevant sampling principles, the most applicable statistical methods, rigorous design and conduct of the data collection and analysis plus careful interpretation of results, and full and open reporting to support peer review and replication. Finally, the researchers should demonstrate adherence to ethical principles and applicable best practice definitions, both in statistics and in the subject matter discipline(s).<sup>9</sup>

The full taxonomy can be outlined as follows:

- Best Practices – which still may be challenged either properly or improperly
- Strict Honest Error – when bad things happen to good, honest and diligent statistical practitioners\*  
\*Competent “statistical practitioners” include, but are not limited to, competent statisticians.

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Statistics continued from page 1)

- Looser Honest Error – when bad things happen to good and honest researchers who, nonetheless, could have been more diligent. For example, they may use data prepared by others without fully understanding the definitions, the sampling plan and the processes used to prepare the data for analysis.
- Honest Negligence – when bad things happen predictably due to more marked deficits of competence or diligence. For example, failure to verify assumptions about the data or to conduct sufficient exploratory data analysis tend to indicate lack of due diligence.
- Generally Accepted, But Incompetent, Statistical Practices – typically seen in researchers who need help with their statistical work, but fail to obtain it. Included here are: the collection of data without a statistically valid sampling plan,\*\* failure to consider and adjust for confounding factors, or orienting statistical work toward an outcome (e.g. p-value less than 0.05) rather than toward methodological validity. \*\* Applies to prospective studies but not necessarily to retrospective studies.

- Gross Negligence – Funding sources, both public and private, can be guilty of this to the extent that, for example, they demand literature citations indicating p-values less than 0.05 in prior related work, but fail utterly to assess the credibility of those values before awarding grants. Similarly, journals may require such p-values in papers but neglect any competent review of the credibility of those numbers. In fact, such practices create a climate of incentives to cheating – as long as the cheating is “merely” statistical.
- Research Misconduct – duplicitous misuse or misreporting of statistical methods through intent to deceive or through culpable negligence. Interestingly, no practice that is “generally accepted” can be “misconduct,” by definition.

**Recommendations for Improving Research Integrity in Statistical Practice**

In keeping with the thrust of the IOM report on research integrity and in employing the taxonomy above, here are recommendations for steps to be taken by research institutions, funding sources, journals, and statistical software makers. These would contribute to improving the overall climate of research integrity.

- Institutions – Define expected standards of research quality, including references to statistical practices and ethics. Provide initial education, training available to junior and senior researchers alike, and remedial training when standards are not met.
- Funding sources – Pay attention to the credibility of statistical competence, methods, and prior results within grant application proposals. Do not accept published/claimed p-values unless they have been credibly peer reviewed.
- Journals – Provide for competent statistical, as well as subject matter, peer reviews and encourage authors to assure that data and study designs be available to statistical and other peer reviewers.
- Statistical Software Makers – Cease any claims that their software will provide valid statistical analyses in the absence of user understanding of the statistical theory and methods being applied. Document the

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algorithms used by their software and assure that the algorithms compute properly.

**As for the Rest of Us**

Ultimately, we as scientists can never rely on the “authorities” to make things right, can we? We all share a responsibility for critical thinking and critical appraisal. We all have to understand at least the elements of statistical theory and statistical thinking and apply them to what we read as well as to what we do. Recognize that bad statistical work is seldom truly attributable to “honest error,” and it can sink to the level of actionable research misconduct. Do not accept inferior statistical work from colleagues, publications, or ourselves. Never be afraid or embarrassed to ask for statistical help when needed.

Above all, we must recognize that sound science can never result from unsound statistics.

**References**

<sup>1</sup> Department of Health Education and Welfare, *The Belmont Report* (1979) <http://ohsr.od.nih.gov/mpa/belmont.php3>

<sup>2</sup> NAS, *Responsible Science*, Vol. 1 (1992) <http://www.nap.edu/books/0309047315/html>

<sup>3</sup> OSTP, *Federal Policy on Research Misconduct*. [http://www.ostp.gov/html/001207\\_3.html](http://www.ostp.gov/html/001207_3.html)

<sup>4</sup> FASEB, letter to OSTP, December 13, 1999 <http://www.faseb.org/opar/letters/1999/francis.html>

<sup>5</sup> Feigenbaum, S. and Levy, D. M. “The Technological Obsolescence of Scientific Fraud,” *Rationality and Society*, 8(3), 261-276 (1996)

<sup>6</sup> DHHS, Integrity and Misconduct in Research: Report of the Commission on Research Integrity (1995) <http://gopher.faseb.org/opar/cri.html>

<sup>7</sup> The National Academies Press, *Integrity in Scientific Research: Creating an Environment That Promotes Responsible Conduct*, Report of the IOM Committee on Assessing Integrity in Research Environments (2002), p. 3

<sup>8</sup> Sigma Xi, *Honor in Science* (1997)

<sup>9</sup> E.g., American Statistical Association, *Ethical Guidelines for Statistical Practice* (1999) <http://www.amstat.org/profession/ethicalstatistics.html>

International Statistical Institute, *Declaration on Professional Ethics* (1985) <http://www.cbs.nl/si/ethics.htm>

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**SPECIAL FEATURE  
IN MEMORIAM  
DOLLY THE SHEEP:  
DEAD AT SIX  
by Kevin Alleman**



(Photo Courtesy of Edge Foundation, Inc. - <http://www.edge.org>)

Dolly “D” sheep, the first mammal cloned from an adult mammary somatic cell by nuclear transplantation and whose birth heralded a breakthrough in molecular biology that incited consternation over the morality of cloning life, died February 16 at the Roslin Institute in Edinburgh, Scotland after suffering from progressive lung disease. She was 6.

Since her birth on 5 July 1996, Dolly ewe-d and awed scientists and the public the world over with her sui generis pedigree: a genetic facsimile of her Fin Dorset sheep “mother.” Like the country music star she was named after—Dolly Parton—one could say that Dolly (“D” sheep) was destined for stardom.

Although her birth was unconventional, Dolly appeared not so different from other little lambs. On the contrary, she lived anything but a quiet life, reaching celebratory status as evinced by international headlines. And like most Hollywood celebrities she grew up in front of the camera, always on display for an admiring public. Her august presence was the focus of the limelight, though almost eclipsed by the birth of her first lamb, which convinced doubters that cloned mammals can reproduce vibrant offspring the natural way.

Her life, however, was not all glamour and glitz. While narrowly escaping the devastating foot-and-mouth disease that swept through the United Kingdom in 2001 by quarantine, Dolly’s health was failing. She was diagnosed with arthritis and later progressive lung disease that ultimately led to her termination. Was the proof in the pudding—that her unique genetic dossier was to blame for the pangs of premature aging? No one knows just yet, as the postmortem investigation is ongoing. Nonetheless, the world anxiously awaits the results.

For better or for worse, Dolly will be remembered by history’s pages as the

archetype of a scientific paradigm shift. As such, she has left a mark, or more precisely a hoof-print on the sands of time, as an embodied artifact dressed in sheep’s clothing. For Dolly “D” sheep will not simply be relegated to remembrance, a relic of the past. Rather, she will be visible to all, as she is to be stuffed for display in the national museum in Edinburgh, perhaps as a monument immemorial to the public interest: as Scotland’s very own “Dollywood.”

*Quiescat in pace agnus Dei.*

Dolly is survived by her six lambs and her estranged suitor, David, the Welsh mountain ram.

## IN THE NEWS

### AAU STATEMENT ON ACADEMIC FREEDOM DURING TIMES OF HEIGHTENED TENSIONS

On January 15, 2003 the Association of American Universities (AAU) released a statement urging academic institutions not to lose sight of their commitment to academic freedom as America prepares itself for war.

This statement entitled, “The Responsibility of Universities at a Time of International Tension and Domestic Protest,” voiced the concern that, “Supporters of various causes and points of view seek adherents and vehicles for their messages, including our universities themselves.” It stressed the importance of university protection of free speech and the maintenance of open environments for learning during times of war. Also, the statement urged universities to further their responsibilities in two additional areas in order to prepare their campuses for possible adverse events.

First, AAU suggested universities should actively promote informed dialogue, analytical thought and exemplary arguments via appropriately guided information sessions. “It is incumbent upon the university to offer the expertise and experience of its faculty and staff members to broad audiences on campus through fora such as teach-ins and seminars,” the statement said.

Second, AAU would like to see universities establish clear boundaries for public protest, being particularly careful to outline the consequences for illicit disruptions such as violence, prevention of class, takeover of buildings, and email fraud, all of which should be prohibited.

The statement asked university presidents, faculty, and students to reaffirm their underlying reasons for being on campus: the work of learning, teaching, scholarship and

research, uninterrupted by anyone.

“For the university to fulfill its obligations to academic freedom and to intellectual development, it must provide a forum in which individuals and groups can advocate their views,” the statement stated. “It must assure an environment for civil discourse to take place free from violence and intimidation.”

The statement by AAU can be found at: <http://www.aau.edu/resources/aaustate1.15.03.html>. \*MP

### NIH RELEASES STATEMENT ON SHARING RESEARCH DATA

In late February of this year, the National Institutes of Health published its final statement on sharing research data. The statement is a result of a NIH review of the comments regarding the draft statement, which began in March of 2002.

The final statement differs from the draft statement in three instances. The first change pertains to the effective start date of the policy changed from January 1, 2003 to October 1, 2003.

Second, applicants seeking \$500,000 or more in direct costs in any year of the project period are expected to contact NIH program staff prior to submission and to include a data sharing plan in their application. The plan should state how they will share their data, and if data sharing isn’t possible, an explanation of why that is so.

Third, in response to objections by several groups and individuals to the sharing of research data prior to publication, NIH has modified the definition of “the timely release and sharing” to be no later than the acceptance for publication of the main findings from the final data set. This change was made to recognize the effort of the investigators who collect the data, but NIH insists that investigators may not benefit from prolonged exclusive use of data.

Public sharing of research data is a long-standing policy of NIH, which believes that the practice is essential for advancing research results and improving human health. However, NIH recognizes that the rights and privacy of research participants in NIH-sponsored research must be protected at all times and that data be free of identifiers before it is shared.

For additional information on NIH data sharing, see [http://grants.nih.gov/grants/policy/data\\_sharing/](http://grants.nih.gov/grants/policy/data_sharing/). \*BP

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## THE NIH-RAC CONVENES ON THE SECOND SERIOUS ADVERSE EVENT IN THE STUDY OF GENE TRANSFER TRIALS IN X-SCID

On February 10, 2003, the RAC met and discussed the findings that a second child involved in the X-SCID study had developed leukemia. Dr. Alain Fisher, who began this study nearly three years ago, joined the conversation briefly via a teleconference voicing his concern for those children still remaining in the study and for the future of gene transfer therapy in general. At the end of the day, the RAC concluded that the gene transfer was a cause of both leukemias, noting that there could be other causes as well. The RAC suggested, pending further data or extenuating circumstances that retroviral gene transfer for X-linked SCID be limited to patients who have failed identical haploidentical stem cell transplantation or for whom no suitable donor can be identified. They found that resumption of non-X-linked SCID gene transfer studies may be justified contingent upon appropriate informed consent and monitoring plans. Finally, they concluded that there is not sufficient evidence at this time to warrant cessation of other retroviral gene transfer studies, which would be contingent upon appropriate informed consent and monitoring plans as well.

More information about the RAC and about the X-SCID gene transfer studies can be found at <http://www4.od.nih.gov/oba/rac/meeting.html> \*MP

## VALUE OF EDITORIAL PEER REVIEW QUESTIONED

Despite its widespread use and costs, the Cochrane Collaboration has found that “there is little empirical evidence to support the use of editorial peer review as a mechanism to ensure quality of biomedical research.” Editorial peer-review is used world-wide as a quality assessment instrument in the selection of submissions to biomedical journals.

The Cochrane report titled “Editorial Peer Review for Improving the Quality of Reports of Biomedical Studies” reached this conclusion after reviewing the effects of the processes of editorial peer-review on original research studies submitted for paper or electronic publication in medical journals.

Results show that factors such as a referee’s training, electronic communication media, and

the practice of concealing the identities of peer-reviewers and authors have little or no effect on the outcome of the quality assessment process.

Similarly, in an attempt to address current questions pertaining to the benefits of the editorial peer-review process and public concern regarding reliability of scientific information in the media, the Royal Society, Britain’s leading academic scientific institution, will investigate the peer review process of scientific literature. It will consider possible failings in the current mechanism for peer review, explore alternatives, and provide direction for the general public on judging the significance of a report on new research.

The Society will also address concerns relating to research results leaking to the media before undergoing peer review. The culmination of the investigation will result in two chief documents – a set of guidelines outlining proper methods of releasing results of scientific research and a “Science Brief” offering practical advice to the public on interpreting the importance of scientific results.

An abstract of the Cochrane report is posted at <http://www.cochrane.org>

The Royal Society can be found at <http://www.royalsoc.ac.uk> \*BP

## ETHICS, LAW AND PUBLIC POLICY

### EVERYTHING OLD IS NEW AGAIN: CONGRESS, CLONING, AND THE NEED FOR REGULATION

By Brent Garland

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The U.S. Congress, which considered but failed to pass a law regarding human cloning last year<sup>1</sup>, has again taken up the issue of what to do about one of the most controversial and contested areas of research in the U.S. Similar to the course of events last year, the House of Representatives has passed a bill (the “Human Cloning Prohibition Act of 2003,” or the Weldon-Stupak bill) that would outlaw all human cloning, both reproductive and research cloning<sup>2</sup>, and provide for both civil and criminal penalties.<sup>3</sup> In addition, the Weldon-Stupak bill would prohibit the importation, shipping, or receiving of cloned embryos or on

any products derived from cloned embryos. The bill authorizes a study by the General Accounting Office (G.A.O.) to assess the need for possible amendment of the ban, considering such factors as developments in medical technology, the need for research cloning in medical advances, as well as current public attitudes and ethical views. The G.A.O. would be required to report back within two years. The Senate has a companion measure<sup>4</sup> to the bill passed in the House that would similarly make both reproductive and research cloning illegal, but it is uncertain as to whether it will reach a floor vote.<sup>5</sup>

The Senate also has a bill (the “Human Cloning Ban and Stem Cell Research Protection Act of 2003” or the Hatch-Feinstein bill), as it did last year, that would ban reproductive cloning, while explicitly permitting human research cloning to move forward.<sup>6</sup> The Hatch-Feinstein bill sets a limit on the number of days that a cloned embryo could develop in vitro—no more than 14 days.<sup>7</sup> Additionally, the Hatch-Feinstein bill provides for G.A.O. oversight reports on the actions of the Attorney General of the U.S. to enforce the bill, on actions of state Attorneys General, on coordinated federal-state enforcement actions, and on international laws related to human cloning. The Hatch-Feinstein bill, which specifically defines “human cloning” as reproductive cloning<sup>8</sup>, is framed in its very title as a way to specifically allow and protect human stem-cell research, as research cloning is likely to play a substantial role in developing new stem cell lines.

It seems unlikely that the Congress will come to a compromise agreement on research cloning this term, despite some two years of hearings and repeated proposed legislation. The gulf in perspectives between those who seek a total ban and those who support research cloning efforts is too substantial to be overcome without significant compromise on both parts. Those who would propose to ban cloning often invoke a “parade of horrors,” including the commodification of the human body, the destruction of embryos for profit, the potential for contamination of the human gene pool, and the likelihood that rogue reproductive cloning will occur if research cloning is permitted. Supporters of research cloning, on the other hand, tend to invoke a “wealth of possibilities,” including substantial advances in the understanding of genetics, embryonic development, and cellular differentiation mechanisms, all of which will theoretically result in an array of medical treatments and cures for disease. The rhetoric often turns pointed, portraying research supporters as amoral “bio-zealots,” driven by

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greed and the technological imperative<sup>9</sup>; while those opposed to cloning are cast as “technophobes” and “bioluddites” who fear the unknown.<sup>10</sup>

The scientific and policy communities, in consultation with a broad range of public constituencies, should vigorously work to bridge the gap between the “pros and cons” and press for rigorous, comprehensive and enforceable regulation of research cloning. The issue of timing is compelling, and the case for the need seems clear.

Timing is an issue because this research is currently going forward in other countries with governmental approval, most notably in the U.K. and China. While some research cloning may be going forward in the U.S. in the absence of regulatory actions, the ongoing debate and potential for a ban may prevent researchers, institutions, and investors from making serious investments of time and capital until the matter is resolved. Such delays may place the U.S. in the unenviable position of either falling behind in this area of science, or of losing significant scientific talent to those countries where the research is being conducted.<sup>11</sup>

The need for regulation, on the other hand, is evinced by the tenor, furor, and sustained nature of the debate itself. The fact is that both sides have legitimate points. There *is* the potential for significant scientific advances that could substantially ease suffering and improve the lives of many. Likewise, there *is* the risk that some abuses may occur, and that some unforeseeable risks lay beyond the horizon.

Neither side can demonstrate a clear majority view. Regardless, the nature of our representational democracy means that the beliefs of the minority are not run over roughshod by the beliefs of the many, and never is that more true than with contested issues of ethics and morality. That neither side has been in a position to make the forceful case for its position leaves us in this legislative impasse.

For supporters of research cloning, the need for compromise and regulation should be clear: a single disaster in an unregulated field of research could shut the entire field down, leave the public demanding accountability, and possibly set the science back for years to come—essentially affecting the same result as a ban. For those opposed, the case is equally clear: the attempt to enact a ban has been a failure, and if the research goes forward without regulation, the risk of the “parade of horrors” is increased, checked only by market pressures and individual conscience.

The time for regulation is now, and the scientific community should lead the charge in establishing an on-going and inclusive dialogue that results in a framework for sensible and effective regulations.<sup>12</sup>

<sup>1</sup> See, “Human Cloning Attempt Prompts Governmental Reactions,” *Professional Ethics Report*, Volume XV, Number 1, Winter 2002.

<sup>2</sup> Reproductive cloning is cloning done in an attempt to create another human being, whereas research cloning includes all other basic and applied research approaches, such as seeking to understand more fully various cellular processes and mechanisms, embryonic development, and the potential to develop medical treatments and therapies.

<sup>3</sup> H.R. 534, sponsored by Reps. Dave Weldon and Bart Stupak, was passed 241-155 on February 27, 2003.

<sup>4</sup> S. 245, sponsored by Sen. Sam Brownback.

<sup>5</sup> See, for example, “Cloning Debate Undiminished Despite House-Passed Ban,” *CQ Weekly*, March 1, 2003, at p.508, stating that the bill “does not have enough votes to withstand a filibuster, and it is unclear if it will reach a floor vote this year.”

<sup>6</sup> S. 303, whose primary sponsors are Sens. Orrin Hatch and Dianne Feinstein.

<sup>7</sup> The 14-day rule is also the current limit in the United Kingdom, as governed by the Human Fertilisation and Embryology Act of 1990, which was amended in 2001 to include cloning research.

<sup>8</sup> That is, any attempt to transfer a cloned embryo into a uterus.

<sup>9</sup> See, Kass, Leon R. “WHY WE SHOULD BAN HUMAN CLONING NOW. Preventing a Brave New World.” *The New Republic*, May 21, 2001. “Some among us are delighted, of course, by this state of affairs: some scientists and biotechnologists, their entrepreneurial backers, and a cheering clique of sci-fi enthusiasts, futurologists, and libertarians. There are dreams to be realized, powers to be exercised, honors to be won, and money—big money—to be made.”

<sup>10</sup> See, Bailey, Ronald. “Anti-Cloning Disinformation? Desperate opponents try to frighten lawmakers with bogus scares.” *Reason Online*, March 13, 2002. “Kristol and Rifkin fabricate a bogus ethical dichotomy pitting “utilitarians” against those who allegedly “believe in the intrinsic value of human life.” Despite their invidious moral posturing, Kristol and Rifkin do not have a lock on ethical rectitude. The intrinsic value of

human life is a given for all sides in this debate. The battle is really between those who want to use the gifts of human reason and human compassion to ameliorate illness and death and those like Kristol and Rifkin who counsel fatalistic acceptance of the manifold cruelties randomly meted out by nature.”

<sup>11</sup> Research cloning opponents often challenge the idea that the U.S. would lose scientists, arguing that a ban presents a clear moral or ethical line, and that only “rogue” scientists would leave to conduct the research. Such an argument assumes a hegemony of belief that does not exist, as demonstrated by the ongoing debate itself. In addition, it minimizes the moral agency of the scientists themselves, suggesting that scientists are not likely to come to a different decision about the acceptability of the work themselves, and then go to where they might best use their education, training, and talents.

<sup>12</sup> AAAS convened a meeting on “Regulatory Issues Surrounding Human Cloning” on March 11, 2003, which sought to identify some of the issues that must be considered in developing a regulatory scheme. A report from the meeting is available at <http://www.aaas.org/spp/cstc/issues/cloningreport.pdf>

## IN THE SOCIETIES

### AAAS BOARD OF DIRECTORS ISSUES RESOLUTION ON FEDERAL ADVISORY COMMITTEE MEMBERSHIP

On March 3, 2003, the AAAS Board of Directors approved a joint Board-Council resolution regarding membership on Federal Advisory Committees. This resolution addressed the importance of federal agencies receiving scientific, technical, and medical advice representing diverse views in order to make decisions based on the best available scientific knowledge as per the Federal Advisory Committee Act, which requires such committees to be “fairly balanced” in the points of views represented and the functions performed.

AAAS believes that a “fair balance” pertains to competence, disciplinary focus, and political and/or institutional allegiance, among other components. As a result, the organization feels that the selection, removal, or replacement of committee members and the disbanding of committees based on criteria unrelated to stakeholder interests or scientific, technical, and medical issues compromises the integrity of the committees receiving expert advice. The resolution calls for the federal

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government to follow the Federal Advisory Committee Act in obtaining expert scientific, technical, and medical advice to ensure its accordance with of the democratic principles of governance.\*JC

## RESOURCES

### SCIENCE AND SOCIAL CONSCIENCE, IN AN INSPIRATIONAL MIX

by Brent Garland

Distinguished geneticist and microbiologist Jon Beckwith has written a unique and informative memoir that skillfully interweaves two of the most prominent threads of his life: science and social activism. The core story in *Making Genes, Making Waves* begins, after brief comments on how Beckwith began his studies of science, with the history of his early work with lac genes in *E. Coli*, and with his groundbreaking work in gene cloning. But this is primarily a non-technical book aimed at a general audience. Although Beckwith covers the major milestones of his scientific career, he also uses the memoir format to give insight into the career and culture of science—the personalities, the institutions, and the continuing excitement that science inspires in him.

The developing social activism aspects of his scientific career come to the fore in 1969. Concurrent with the publication of a seminal paper on genetics in *Nature*, Beckwith and two of his colleagues held a press conference to warn of the potential dangers of genetic manipulation. As Beckwith notes, this press conference was reflective of the joining of his political and scientific lives. The publicity storm that followed, along with the critical reactions from fellow scientists, may have been Beckwith's first experience as the focus of public controversy, but it would not be the last.

Indeed, while Beckwith does an admirable job of tracing his major discoveries and the development of his scientific career (and in a general, non-technical style that makes it fully accessible to any one with a basic knowledge of science), the most compelling parts of the book are the ones chronicling his social activism and often, the resulting uproar. Beckwith's involvement with scientific ethics concerns reads almost like a history of modern science, including work with the social and political ramifications of genetics; with documenting the difficulties of being a scientist in Cuba; with the effort to educate scientists about the horrible legacies of eugenics; with challenging the misuses of genetic science, behavioral genetics and sociobiology (for example, in debunking the

poor science of *The Bell Curve*); and with the Ethical, Legal and Social Implications Working Group of the Human Genome Project.

Beckwith has produced a book for scientists, ethicists, and anyone who is interested in gaining insight into the life of an accomplished scientist and committed social activist. In addition, for scientists, Beckwith's book serves as a model for how a scientific life can include and inform a political life, and illuminates the possibilities for interaction between the worlds of hard science and social activism.

Beckwith, Jon. *Making Genes, Making Waves*. Harvard University Press, 2002.

### TOWARDS A BROADER VIEW OF ACADEMIC ETHICS

by Brent Garland

The privileged position that academics hold in modern American society carries with it corresponding professional responsibilities, and Neil Hamilton has done the academic community a significant service with his new book on academic ethics. While many academicians receive substantive training in the ethics of their discipline (science, engineering, law, etc.), too often the ethical issues of life in the academy are all but ignored. Many young faculty receive a day or two (or if lucky, a week) of training at the beginning of their careers that is related to appropriate interactions with students, administrators, and colleagues. All too often, the "ethical lessons" are boiled down to three points: don't plagiarize, don't have sex with your students, and don't steal from your grant funds. While these points are undoubtedly good advice, the failure to provide substantive education on the ethical practices and principles of academia as a whole does students and faculty a grave disservice. Graduate students, new professors and experienced faculty alike can benefit from Hamilton's thought-provoking analysis of the ethical duties and correlative rights of academics, both as individuals and as a collegial body.

Tightly organized in a format that makes it ideal for a graduate seminar or an ongoing faculty discussion group, Hamilton presents first an analysis of the duties and rights of faculty, supplemented and illuminated by comparisons among some relevant documents, including the 1915 General Declaration of Principles of the American Association of University Professors (AAUP), the 1940 AAUP Statement of Principles on Academic Freedom and Tenure, and the 1998 Statement on Institutional Governance by the Association of Governing Boards (AGB). Hamilton

uses these documents to help provide a historical and cultural context for the development of current concepts of academic ethics.

In his analysis, Hamilton lays out a framework for considering the ethical behavior of academicians, focusing on the right of the faculty to free speech, peer review, and shared governance, and the duties of professional competence and ethical conduct. Hamilton follows this analysis with chapters that borrow the "case method" of business and legal education. Each chapter contains numerous vignettes (which Hamilton terms "problems") that pose ethical questions for those involved, followed by series of discussion questions. The chapters are organized by the types of problems they present in Hamilton's framework: the duties of individual professors; the rights of individual professors; the duties of professors as a collegial body; the rights of the collegial body; and the rights of students.

Hamilton's choice to use a "case method" format should be effective for maximizing discussion, and is a real asset in helping to provide numerous examples of potentially problematic situations. The questions that follow each "problem" serve to identify and frame key ethical issues present in each vignette.

Following the "case method" chapters are a rich and useful set of appendices that contain the AAUP and AGB documents relevant to the initial part of the book. Provision of these texts are a useful tool for the reader who wishes to consider Hamilton's analysis in a more full context, or for faculties seeking to draft their own statements on similar academic ethics issues.

If this book has one weakness, it is that Hamilton's chapters on "problems" consist solely of that: problems, followed by questions, with no additional analysis or commentary by the author. Given Hamilton's expertise and deep thinking evinced on the subject in the initial chapters, readers could likely benefit more from his knowledge if he offered some model analyses of a subset of the problems presented. That said, Hamilton's book is a valuable resource to anyone with either a scholarly or practical interest in academic ethics.

Hamilton, Neil W. *Academic Ethics. Problems and Materials on Professional Conduct and Shared Governance*. American Council on Education/Praeger Series on Higher Education, 2002.

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(Resources continued from page 6)  
**ARE WE CREATING A WORLD WE  
DON'T WANT TO INHABIT?**

by Deborah Runkle

This is but one of many questions asked in *Bloodlines*, a video due to appear on PBS on June 10, 2003 (check local listings). Produced, written, and directed by Noel Schwerin of Backbone Media, *Bloodlines* presents a series of case studies that examines what happens when life science technologies raise ethical, social, and legal dilemmas. The video is divided into three scenarios presenting real life situations. The actual personae in these situations tell their stories, with commentary by legal scholars and practitioners.

The first scenario asks *Who Is a Parent?* Reproductive technologies intended to help infertile couples have a baby are now a familiar and widely accepted practice. Nevertheless, the various permutations of donor sperm, donor egg, and donor uterus pose continuing challenges for family law, challenges that are playing out in courtrooms and in the lives of adults and babies. The cases presented in this segment address the following dilemmas:

- The baby with five parents: A married couple with fertility problems is unable to have a baby of “their” own following six attempted *in vitro* fertilizations and six surrogates. They eventually “conceived” a baby with donor sperm, donor egg, and a surrogate mother. However, during the pregnancy the husband decides to divorce his wife, renouncing all parentage and responsibility for the yet-to-be-born child. Is he the legal father with concomitant responsibilities?
- The babies with two mothers: Wishing to have a family, a lesbian couple “conceives” three children using eggs from one partner and the uterus of the other, plus donor sperm. Do the two “mothers” have equal legal rights and responsibilities in relation to “their” children?
- The twins whose “parents” change their minds: An infertile couple hires a surrogate to bear

a child for them, a woman who was a surrogate for them on a previous occasion and who has also been a surrogate for other couples. Pregnant with twins, the surrogate learns that the couple is having marital difficulties and intends to place the twins in foster care. The surrogate wants to find a permanent, adoptive home for the twins. Does she have any rights regarding what happens to “her” babies?

The second scenario asks *What Is Human?* This scenario presents two provocative cases that illustrate the ethical and legal difficulties that can arise with technologies that allow the combining and crossing of species.

- A developmental biologist has filed a patent application on an embryo that is a chimera, part human and part chimpanzee. Increasingly uneasy about the directions in which research in his discipline are heading, he has taken this action to force a public review of the patentability of living organisms. Stated simply, how many cells does it take to make an organism human?
- A man desperately ill with Parkinson’s disease agrees to a procedure that implants pig cells into his brain. Although his medical condition is dramatically improved, what does it mean to have the cells of another species functioning in his body?

The final scenario asks *Who Has Rights?* While genetic testing holds great promise for improving our lives, our society has yet to reach a consensus about when such testing is useful, even desirable, and when it is harmful or poses an intrusion into an individual’s privacy. Two railroad workers, along with more than a hundred of their co-workers, file for workman’s compensation due to carpal tunnel syndrome that they claim is a result of the repetitive motions required by their jobs. Their employer takes blood samples and, unbeknownst to the employees, conducts genetic testing on the blood. Who has a right to our genetic information and how can they use this information?

*Bloodlines* offers no easy answers to these questions, but it does provide an opportunity for viewers to ponder them. This series of ethical, social, and legal dilemmas will best be used in classrooms and other educational settings.

For more information see [www.backbonemedia.org/bloodlines](http://www.backbonemedia.org/bloodlines).

*On May 14, at 4 p.m., Bloodlines, along with A Question of Genes, a previous PBS documentary from the same producer, will be presented at AAAS headquarters. Portions of the videos will be shown, with reactions from legal and bioethical scholars.*

## ANNOUNCEMENTS

Meeting — The **American Association for the Advancement of Science and the Hastings Center** are hosting “Can We Talk? A Public Conversation About Behavioral Genetics and Society,” May 2-3, 2003, in Washington, DC. This meeting will explore some of the central controversies surrounding research on the association between genes and behavior, from devastating mental diseases to aggression and personality. Leading scientists in the field, ethicists, legal scholars, patient advocates, and journalists will examine issues ranging from what science can really tell us regarding genetic explanations for behavior, to notions of “free will,” to the use of research findings in the criminal justice system, to how to foster conversations on these controversial matters between scientists and the general public. The meeting will employ a number of strategies to engage the audience, including the showing of the video, “Genes on Trial,” the use of audience response technology, and a roundtable featuring scientists, journalists, and policy makers discussing the roles and responsibilities of various parties in communicating scientific information to the public. For more details and to register (it’s free!), visit the conference web site at <http://www.aaas.org/spp/bgenes/cwt>.

Symposium — The **National Human Genome Research Initiative** is holding a half-day public symposium entitled “Bringing the Genome to You” on April 15, 2003 in Washington, DC. Registration and information are available at WWW <http://www.genome.gov/About/April/Public>.

Conference — The Institute for Applied and Professional Ethics at Ohio State University announces its third **Student Conference on Applied Ethics** to be held April 26-27, 2003. The keynote address will be “Cheating” by Bernard Gert of Dartmouth College. For details, visit WWW <http://www.ohio.edu/ethics>.

Conference — The **National Patient Safety Foundation** will hold their 2<sup>nd</sup> Annual Clinical Research Conference on Integrity and

(Announcements continued on page 8)

# Professional Ethics Report

Scientific Freedom, Responsibility and Law Program  
American Association for the Advancement of Science  
1200 New York Avenue, NW, Washington, DC 20005

Accountability in Clinical Research on May 6-8, 2003 in Washington, DC. Symposia include Preservation of Privacy and Dignity of Research Subjects and the Impact of Bioterrorism on Clinical Research. For more information, see WWW <http://www.saferesearch.org>.

Institute — The **Ethics Institute at Dartmouth College**, in collaboration with Howard University, is offering three sessions of a Faculty Summer Institute on Teaching the Ethical, Legal and Social Implications (ELSI) of the Human Genome Project (HGP). Dates are June 15-21 at Dartmouth, July 6-12 at Howard, and August 10-16 at Dartmouth. For more information, visit WWW [http://www.dartmouth.edu/artsci/ethics-inst/elsi\\_index.html](http://www.dartmouth.edu/artsci/ethics-inst/elsi_index.html).

Workshop — The **Hastings Center** is offering an intensive workshop on science and social responsibility on June 20-23, 2003 in Garrison, NY. The project is intended to examine issues related to the societal impact of science that have developed in recent years and to create a network of young scientists who work in these areas. Interested parties should send a letter describing their research experience in dealing with issues of science and social responsibility and indicating if they will need full or partial financial support. The letter should be sent to Daniel Callahan,

Director, International Programs, The Hastings center, 21 Malcom Gordon Drive, Garrison, NY, 10503, 845-424-4040; fax: 845-424-4545; email: [Callahan@thehastingscenter.org](mailto:Callahan@thehastingscenter.org).

Conference — Boston College, Loyola University, Chicago, Holy Cross College, and St. Louis University are co-sponsoring the **Sixth Annual Ethics and Technology Conference** from June 27-28, 2003 in Chestnut Hill, MA. The theme of the conference is Intellectual Property Rights in a Networked World. For more information, visit WWW <http://www.bc.edu/ethicstech>.

Conference — Western Carolina University is holding a conference on **The Science, the Law, Ethical and Social Implications: A Policy Modeling**, from April 2-3, 2003 in Asheville, NC. For more information, email Karen Nicholson at [knicholson@email.wcu.edu](mailto:knicholson@email.wcu.edu).

Workshop — The **Center for the Study of Ethics in Professions (CSEP)** at the Illinois

*Correction:* In the December issue of PER, the review of the book *Trying Times* incorrectly stated that Judge Rothstein serves on the Ninth Circuit Court of Appeals. She serves on the District Court for the Western District of Washington. We apologize for any confusion or inconvenience this error may have caused. -- Eds.

Institute of Technology will host Ethics Across the Curriculum, a Practical Workshop on how to integrate ethics into technical courses from June 24-July 1, 2003 in Chicago, IL. Application consists of a) a short letter describing reasons for wanting to take the workshop, applicant background, and the courses applicant will be teaching next fall; b) a CV; c) a letter of commitment from the appropriate administrator indicating that the applicant's institution will pay its share of the \$2000 stipend if accepted. Deadline for application has been extended. Contact Michael Davis, Center for the Study of Ethics in the Professions, Illinois Institute of Technology, Chicago, IL 60616-3793; (312) 564-3017; fax (312) 567-3016; Email: [davism@iit.edu](mailto:davism@iit.edu)

Call for Articles — The **Center for the Study of Ethics of LaRoche College** is inviting articles for its next issue of *Sensibilities*. The topic of the issue is "Ethics and Sports." Deadline for submissions is August 15, 2003. Articles should be submitted to Casey Kutcher at [ethics@laroche.edu](mailto:ethics@laroche.edu). For more information, visit WWW <http://intranet.laroche.edu/external/ethic> or contact Michael C. Brannigan, Executive Director, Center for the Study of Ethics, LaRoche College, Pittsburh, PA 15237, 412-536-1209, email: [branim1@laroche.edu](mailto:branim1@laroche.edu).

Call for Papers/Conference — The **ELSA National Research Program** is presenting a conference on Perceptions and Evaluations of Gene Technology from December 4-5, 2003 at Linkoping University in Sweden. The focus of the conference is the the ethical, communicative and sociological issues in relation to individual and public perceptions of gene technology. Abstracts (500 words or less) should be submitted by ordinary mail and email to Professor Lennart Nordenfelt, Department of Health and Society, Linkoping University, 58185 Linkoping, Sweden, email: [lenno@ihs.liu.se](mailto:lenno@ihs.liu.se)

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