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EMBRYONIC STEM CELLS: CURRENT DEBATE AND FUTURE DIRECTIONS

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As the presidential election approaches, one of the few scientific issues to attract political debate is that of embryonic stem cell research. Although embryonic stem cell research and technology is in its infancy, it has provoked widespread public and professional debate, exemplified by the plethora of articles exploring the morality of embryonic stem cell research, policy surrounding the research, international positions, etc. In this essay, I will engage in a brief overview of the research, some recent developments, the political climate in the U.S., and finally the importance of public education, concluding with my views.

Brief Background

The use of embryonic stem cells for research is a practical research activity involving moral issues at its core. For those who believe that personhood begins at conception, destroying an embryo to retrieve its pluripotent stem cells is tantamount to murder of a living being and a moral crime. For those who do not see it this way, the potential fruits of the research may eventually outweigh the harm in destroying the embryos. Despite these characterizations, there is undoubtedly an array of beliefs among scientists, medical ethicists, and the public, and all viewpoints should be heard, considered, and respected. Scientists hope, and have reason to believe, that embryonic stem cells may one day be used to cure or effectively treat a range of diseases, from diabetes mellitus to Parkinson's disease, where cells themselves or particular cellular activities are lost. Sources of stem cells may come from embryos left-over from in vitro fertilization (IVF) treatments as well as from embryos created by the same process, but for research and not fertility purposes. When stem cells are retrieved from an embryo that was created through somatic cell nuclear transfer, or SCNT (also referred to as "therapeutic cloning" or "research cloning"), this means that the nucleus of an egg has been extracted (the egg may originate from the patient or other donor) and the nucleus of a patient's somatic cell is inserted into the egg. Stem cells are then extracted from the resulting blastocyst. Scientists and patients alike anticipate this process will enable the growth of tissue with the patient's genetic material, thereby significantly reducing the possibility of recipient rejection of transplanted cells and tissue.

The current U.S. policy, in the form of an Executive Order, was instituted by President George W. Bush in addressing the nation on August 9, 2001. It forbids the allotment of federal funds to research on embryonic stem cells derived after August 9, 2001, but allows federal money to be used to investigate stem cell lines[1] existing prior to that date that meet certain criteria. There has been considerable uncertainty as to the number of lines available for federal funding, as well as the quality and genetic diversity of the available cells.[2] There is no restriction on research supported by private funds.

Some Recent Scientific Developments

A team from Johns Hopkins University used the H1 human embryonic stem cell line (available for federal funding) to differentiate[3] the stem cells into leucocytes with antigen-presenting function. They sought to address the issue of recipient rejection of potential therapies derived from human embryonic stem cells of genetically distinct donor and recipient.[4] In February of this year, the world learned that researchers in South Korea developed a line of human embryonic stem cells from the process of SCNT.[5] Perhaps the most scientifically useful of the recent advances comes from Harvard University, where researchers derived and characterized 17 new human embryonic stem cell lines from embryos produced by IVF "for clinical purposes." These cell lines were developed using funds from the Howard Hughes Medical Institute (among other sources).[6] In the same issue of the New England Journal of Medicine in which the creation of the new cell lines was reported, others voiced the opinion that the lines should become eligible for research with NIH funds.[7]

U.S. States

Currently, two state laws specifically promote embryonic stem cell research. California is one, and its laws allow for the creation of embryos by SCNT.[8] Proposition 71 "authorizes tax-free state bonds that will provide an average of $295 million per year over ten years to support stem cell research at California universities, medical schools and research facilities."[9] The vote on this ballot initiative will take place in November 2004.

Earlier this year, New Jersey adopted a law allowing human embryonic stem cell research, which also permits the produc-

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tion of embryos by SCNT.[10] In addition, the Governor created The Stem Cell Institute of New Jersey, which is the "first state-supported stem cell research institute."[11]

Other states are deciding whether to ban, allow, or restrict the research, and many bills have been introduced on the topic.[12] The National Conference of State Legislatures reports that current state laws are very diverse, and some states restrict research activities based on the source of the embryo. An example of a highly restrictive policy exists in South Dakota, which bans embryo research completely.[13] In the absence of broader federal funding, state action, especially in states with the resources and facilities to conduct research, may prove to be essential in allowing U.S. scientists to do what is often permitted abroad.[14]

The Political Climate in the U.S.

The stem cell debate has permeated politics and become an election-year issue. President Bush has stood by his original decision. The moral status he accords to human embryos shapes his view that the government - via federal funding - should not be complicit in their destruction.[15] The Democratic nominee, John Kerry, has pledged to overturn the ban on federal funding of new cell lines.[16] Finally, Ron Reagan, son of the late President, has publicly declared his support for stem cell research, as he watched his father fade irreversibly from Alzheimer's disease. It would be useful to know the extent to which U.S. researchers have diverted research interests from embryonic stem cells in order to pursue other, fundable projects. Anecdotal evidence suggests that researchers relocate to pursue their work where the policies are more permissive,[17] and within the U.S., researchers will likely be attracted to New Jersey and California (especially if the people of California vote for Prop. 71). However, statistics describing this potential trend could prove useful to evaluate the effects of current state and federal policy.

Public Education

A *Lancet* editorial encourages scientists to engage in public dialogue about stem cell research.[18] Members of the public undoubtedly have been exposed to a variety of views. The media, politicians, and those with personal stories, such as activist Christopher Reeve, help to shape the public's perception of science and its potential benefits. However, claims that the technology could be used to produce clones for spare body parts likely infuse fear and skepticism into public opinion. Public education is the key to not only alleviating fears of scientists' intentions, but also for explaining the use of embryos in this research in terms the public can understand and appreciate, whether or not their tax dollars will help fund the work.

A Personal Perspective

Currently, embryonic stem cell research is young but promising. Private and state funding and the available stem cell lines may be adequate for the time being. However, if the U.S. is to be on the cutting-edge of medical and scientific breakthroughs emerging from stem cell research, federal funding will likely be essential. Scientific freedom has been invoked as a means through which stem cell policy should be examined.[19] Despite the research conducted by Zhan, et al. (see note 4) using a federally-fundable cell line, the full promise of this team's work relies on the premise that stem cell-based therapies will be developed. Some suggest that the disparity between the President's policy limiting federal funding and the fact that much can be done with private money warrants regulation of some kind, whatever it may be.[20] I support a policy that allots federal funding to research involving embryos from SCNT and those created by IVF to increase the number and

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EMBRYONIC STEM CELLS: CURRENT AND FUTURE DIRECTIONS

The political climate surrounding the 2004 election has provided incentive for public figures from different sides of the political and religious spectrum to discuss openly embryonic stem cell research. The widespread debate over the current Administration's embryonic stem cell policies—which limits federal funds to support research on only a small group of specified embryonic stem cell lines—in addition to the upcoming Presidential election, has led to a dramatic increase in public awareness of embryonic stem cell issues since 2001, when the current policy was instituted.

Coinciding with the increase in general public awareness, there has been an increase in the proportion of supporters for embryonic stem cell research, regardless of stem cell lines used, among people in both political parties and who come from different religious backgrounds.

The following are results from a nation wide online survey of 2,242 adults between July 12th and 18th, 2004: ("The Harris Poll #58, August 18, 2004" http://www.harrisinteractive.com/harris_poll/). **TJ*

	2001 (%)	2004 (%)
Issue Exposure		
Those who have seen, heard, or read about the debate on stem cell research	68	83
Those who have not been informed, or who are unsure	32	17
Issue Opinions		
Those who believe that stem cell research **should** be allowed to continue	61	73
Those who believe that stem cell research **should not** continue	21	11
Current **Republicans,** **Democrats,** and **Independents** who: **support** stem cell research (respectively).		60, 80, 83
DO NOT support stem cell research		18, 5, 7
Those who believe stem cell research is **unethical** and should be **forbidden**	32	19

Letters to the Editor: The editors welcome comments from our readers. We reserve the right to edit and abridge letter as space permits. Please address all correspondence to the deputy editor.

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diversity of cell lines available. Parameters would be required to ensure ethical oversight, such as protection of those donating gametes (if a policy permits use of embryos created for research purposes through IVF) or embryos left-over from IVF during fertility treatment.

Regardless of where the President's Order or Congressional action takes us, a number of policy issues remain to be resolved. For example, how will the FDA evaluate clinical trials using both federally sponsored embryonic stem cell research (if this indeed is possible given the limitations of the approved lines) as well as investigative biologics derived from privately funded research? Also, if therapies are developed abroad using embryonic stem cells not accessible to American scientists, would the U.S. government attempt to limit access by patients in this country? How would states with restrictive policies deal with this issue?

In conclusion, the stem cell controversy ignites deep emotions among those who believe embryos are human beings deserving of full protection and among those who hope to draw upon the fruits of embryonic stem cell research. The possible extraordinary benefits of this research to elucidate the basic science of human development, bases for disease, and differentiation processes as well as to alleviate the suffering of those afflicted with many diseases are considerable. Such research should not be held hostage by a policy based on the moral status of the embryo, and American scientists should not be forced to go elsewhere to pursue this potentially valuable research.

[1] See http://stemcells.nih.gov/research/registry/.
[2] See, *e.g.*, Siegel, A., Temporal Restrictions and the Impasse on Human Embryonic Stem-Cell Research. *Lancet*, July 10, 2004, p. 215-18.
[3] "Cell differentiation" may be defined as "[t]he process during which young, immature (unspecialized) cells take on individual characteristics and reach their mature (specialized) form and function." This definition was found at http://www.myeloma.org/myeloma/kb_index.jsp?type=detail&id=611.
[4] Zhan, X. et al., Functional Antigen-Presenting Leucocytes Derived From Human Embryonic Stem Cells In Vitro. *Lancet*, July 10, 2004, p. 163-171.
[5] Vogel, G., Scientists Take Step Toward Therapeutic Cloning. *Science*, Feb. 13, 2004, p. 937, 939.
[6] Cowan, C. et al., Derivation of Embryonic Stem-Cell Lines from Human Blastocysts. *N. Eng. J. Med.*, March 25, 2004. Downloaded from nejm.org March 3, 2004.
[7] Phimister, E.G. & Drazen, J.M., Two Fillips for Human Embryonic Stem Cells. *N. Eng. J.* Med., March 25, 2004. Downloaded from nejm.org March 3, 2004.
[8] CA Health and Safety Code §125300. See http://www.leginfo.ca.gov.
[9] http://www.curesforcalifornia.com
[10] McGreevey Signs Landmark Stem Cell Research Act. NJ Office of the Governor Press Release, January 4, 2004. http//www.state.nj.us/cgi-bin/governor/njnewsline/view_article.pl?id=1668.
[11] McGreevey Creates Nation's First State-Supported Stem Cell Institute. NJ office of the Governor Press Release, May 12, 2004. http//www.state.nj.us/cgi-bin/governor/njnewsline/view_article.pl?id=1910.
[12] See States are Wrestling with Stem-Cell Issues, April 6, 2004, *Chicago Tribune*. http://www.chicagotribune.com.
[13] http://www.ncsl.org/programs/health/genetics/embfet.htm.
[14] The following are two examples of permissive policies. Israel is an example of a country that has prohibited reproductive cloning but whose laws state nothing about therapeutic cloning, considered to be permissive. In the UK, legislation draws the prohibitive line at putting an embryo created by means other than fertilization into a woman. See Tauer, C., International Policy Failures: Cloning and Stem-Cell Research. *Lancet*, July 10, 2004, p. 209-14.
[15] See http://www.georgewbush.com/HealthCare/Read.aspx?ID=3095.
[16] See http://www.johnkerry.com/issues/health_care/stemcell.html.
[17] See Pincock, S., Britain's Brain Gain. *Lancet*, July 10, 2004, p. 127-28. Note, however, that the article suggests that researchers who moved to countries with more favorable laws do not believe this will be a major trend.
[18] Editorial., It is Time for Scientists to Make the Case for Stem-Cell Research. *Lancet*, July 10, 2004, p. 113-14.
[19] Caulfield, T., Scientific Freedom and Research Cloning: Can a Ban be Justified? *Lancet*, July 10, 2004, p. 124-26.
[20] See, *e.g.*, comment by Minger in Pincock, S. Britain's Brain Gain. *Lancet*, July 10, 2004, p. 127-28.

IN THE NEWS

ACADEMIES LOBBY ON CLONING

The United Nations (UN) General Assembly is expected to revisit the human cloning issue once again this fall with a vote scheduled for October 21-22.[1] In anticipation of such a decision by the UN's 59th General Assembly, the InterAcademy Panel (IAP), an umbrella body for national science academies based in Italy, has been urging the world's science academies to reaffirm their support for an international cloning treaty that does not outlaw cloning for research. In hopes of stepping up the pressure on its members' national governments, the IAP re-released a statement from last year, signed by 67 of its 90 member organizations, that urges appropriate government officials to leave policy on research cloning up to individual countries.[2]

Britain's Royal Society agrees that there should be an international ban on human reproductive cloning, but that nations should be allowed to make their own decisions regarding research cloning, and joined in with public statements of its own.[3]

"It is clear that if the convention bans all human cloning, the UK, and other countries which permit carefully regulated therapeutic cloning, will not sign up to it," said Richard Gardner, chair of the Royal Society working group on stem cell research and cloning, to *The Scientist*.[4]

The UN's debates on cloning in recent years have been contentious. Last year, countries rallied around two proposals. One proposal, put forward by Costa Rica and supported by the United States, pushed for a total ban on human cloning. The other, proposed by Belgium and supported by the United Kingdom, urged a ban on reproductive, but not research cloning. The lack of consensus led to a motion for a two-year delay. In a rush of last minute discussions, the issue was delayed only one year.

The Royal Society is worried because it isn't sure to what extent scientists realize that the UN will be dealing with the issue this fall. Said Bob Ward, spokesman for the Royal Society, to *The Scientist*: "That's why we're trying to raise consciousness among both the scientific community and policymakers who will be responsible for the approach of various governments." **AK*

[1] See PER, Fall 2003, vol.16, no. 4, http://www.aaas.org/spp/sfrl/per/per35.htm
[2] For statement, see "67 of the world's science academies…" at www.interacademies.net
[3] For press release, see http://www.royalsoc.ac.uk/cloning/
[4] For article from *The Scientist*, see "Academies lobby on cloning" at www.biomedcentral.com/news/20040831/02

BIO JOURNAL MISTAKENLY PUBLISHES INTELLIGENT DESIGN STUDY

In a public statement, the Biological Society of Washington (BSW) is distancing itself from the pages of its own 124-year old journal, *The Proceedings of the Biological Society of Washington.* Much to the dismay of the Society's leadership, a paper "deemed inappropriate" by its council slipped unnoticed into the June issue of its peer-reviewed taxonomy publication.[1]

The paper advocates "intelligent design theory" (ID), which challenges the accepted scientific theory of biological evolution by claiming that complex biological systems could not have arisen through purely random evolutionary processes. ID contends, rather, that an intelligent force must have played a part in the development of the universe and of living things. The paper concludes: "what natural selection lacks, intelligent selection-purposive or goal-directed design provides."

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Critics of intelligent design describe it as old creationist arguments in fancy clothes.

The controversial article, entitled "The origin of biological information and the higher taxonomic categories," was written by Stephen C. Meyer, director of the Center for Science and Culture at the Discovery Institute in Seattle and professor at Palm Beach Atlantic University. The Discovery Institute supports many leaders in the intelligent design movement and promotes teaching the theory in public schools.

The paper was accepted for publication by the journal's previous editor, Richard Sternberg, a fellow at the National Center for Biotechnology Information. Mr. Sternberg is also a fellow of the International Society for Complexity, Information, and Design, which promotes the idea that nature has a purpose. Roy W. McDiarmid, president of the Biological Society of Washington, told *The Chronicle of Higher Education* that including the paper "was a really bad judgment call on the editor's part."[2] The BSW's public statement endorses "the spirit of a resolution on Intelligent Design set forth by the American Association of the Advancement of science."[3]

For some, it is very troubling that the paper had been peer-reviewed by three scientists and recommended for publication pending revisions. "People who would be appropriate to review the paper would be evolutionary biologists," Eugenie C. Scott, executive director of the National Center for Scientific Information, told the *Chronicle*. "And I doubt that any evolutionary biologists reviewed the paper."[4]

The BSW statement also noted that a detailed critique of Meyer's paper can be found on http://pandasthumb.org, a Weblog that focuses on issues in evolutionary science.[5] The review congratulates ID on "finally getting an article in a peer-reviewed biology journal." It then proceeds to highlight errors in facts, reasoning, and the omission of "vast amounts of directly relevant work available in the scientific literature." The debate appears to just be heating up. **AK*

[1] For paper, see "The origin of biological information and the higher taxonomic categories." *The Proceedings of the Biological Society of Washington,* vol. 177, no. 2, pp. 213-239. Republished online at http://www.discovery.org/scripts/viewDB/index.php?command=view&id=217&program=CSC&callingPage=docMainPage

[2] Monastersky, Richard. "Biology journal says it mistakenly published paper that attacks Darwinian evolution." *The Chronicle of Higher Education*, September 10, 2004.

[3] For AAAS Board Resolution on Intelligent Design Theory, see www.aaas.org/news/releases/2002/116id2.shtml

[4] See Note 2.

[5] For critique, see http://pandasthumb.org.

CONGRESS CONSIDERS GENETIC NONDISCRIMINATION LEGISLATION

In October 2003, the Senate unanimously endorsed the Genetic Information Nondiscrimination Act (S. 1053), a bill that protects privacy of genetic information and sets regulations against genetic discrimination in health insurance and employment. The bill has not progressed in the House of Representatives, however. The House has not given genetic nondiscrimination top priority due to the increased demands of other urgent issues (Defense, Homeland Security, Energy), and due to insufficient evidence demonstrating that genetic discrimination is a widespread problem.[1] The House does not want to create 'hasty mandates' without fully assessing the laws already in place to protect against genetic discrimination, or reduce employer incentive to provide high quality health coverage to their employees.[2]

Many organizations that have been instrumental in introducing the bill are continuing to urge its passage. Among these is the Secretary's Advisory Committee on Genetics, Health, and Society (SACGHS). SACGHS will hold a fifth hearing on Genetic Discrimination on October 18, 2004, specifically to better address current impediments to genetic nondiscrimination legislation. The main agenda for the upcoming hearing is to explore the extent of genetic discrimination, and the various constraints that genetic discrimination has imposed on the scientific community and the U.S. population at large. The focus will be on personal accounts from individuals who have experienced genetic discrimination in health insurance and employment, avoided insurance companies by paying out of their own pockets for genetic testing or treatment, and avoided potentially beneficial testing and treatment due to genetic discrimination fears. The committee will also hear from health care providers who have witnessed any of the above. The committee plans to examine the existing bases for genetic discrimination according to: "predictive genetic information," "pre-symptomatic genetic disease," or "carrier status."[3]

Those organizations committed to creating genetic nondiscrimination legislation worry that if legislation is not passed, genetic research necessary to test and treat individuals will be severely compromised. They contend that other high priorities on the SACGHS' agenda, such as 'Identifying the opportunities and gaps in research and data collection efforts', and 'Guidance for practitioners translating genetic technologies into practice', will also be more difficult to address (and less accurate) without the proper federal protective measures in place.[4] **TJ*

[1] Secretary's Advisory Committee on Genetics, Health and Society. "SACGHS Request for Public Comments on Genetic Discrimination". http://www4.od.nih.gov/oba/sacghs/meetings/October2004/Request_for_Comments_Oct2004.pdf

[2] Committee on Education and the Workforce, U.S. House of Representatives. "The Promise and Implications of Genetic Testing — and the Possible Consequences of New Mandates." Genetic Nondiscrimination Issue Brief. July 2004. http://edworkforce.house.gov/issues/108th/workforce/gnd/gnd.htm

[3] Secretary's Advisory Committee on Genetics, Health and Society. "SACGHS Request for Public Comments on Genetic Discrimination". http://www4.od.nih.gov/oba/sacghs/meetings/October2004/Request_for_Comments_Oct2004.pdf

[4] The Secretary's Advisory Committee on Genetics, Health, and Society. "Fourth Meeting". Transcripts. June 14-15 2004. http://www4.od.nih.gov/oba/sacghs/meetings/June2004/SACGHSJun2004postmeeting.htm.

NEW REPORT ON CONFLICT OF INTEREST STANDARDS

On 13 September 2004 a survey released by the Association of American Medical Colleges (AAMC) reported that accredited medical schools in the United States are strengthening their financial conflicts of interest standards in clinical research. Following a AAMC publication in 2001, "Protecting Subjects, Preserving Trust, Promoting Progress: Policy and Guidelines for the Oversight of Individual Financial Interests in Human Subjects Research," which focused on the oversight of individual financial interests in human subjects research, the survey is the second installment from the AAMC task force looking at institutional conflicts of interest in human subjects research.

The survey collected responses over a nine month period to assess the extent to which institutional conflicts of interest policies reflect the 2001 AAMC recommendations. AAMC reported that 95 percent of institutions that responded have a policy that applies to all human subjects research that extends beyond the minimum federal standards. Additional findings include:

- Most institutions have elucidated their conflict of interest standards: 95 percent of which apply to all faculty engaged in human subjects research, regardless of the funding source; and 77 percent include all non-faculty engaged in human subjects research, regardless of the funding source.
- Most institutions are moving toward full disclosure: 98 percent of the

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respondents define a significant financial interest in their policies; 95 percent use the federal government threshold of $10,000 or a lower monetary standard; and 64 percent go beyond federal regulations to consider financial ties to equity in non-publicly traded companies regardless of value, as well as non-royalty payments not directly related to reasonable costs of research.

- Institutions are using a variety of safeguards to help manage conflicts of interest: 85 percent require monitoring of the research; 74 percent require disclosure of a significant financial interest to the human participants in the consent form, and the policies of 86 percent suggest disclosure; and 76 percent have established a standing committee on conflicts of interest.

The survey also highlighted policies and procedures that need further attention. For instance, 40 percent of institutions do not require researchers to disclose financial interests in oral presentations; therefore, the AAMC suggests the need for more inclusive definitions of covered financial interests. Moreover, 9 percent of standing conflicts of interest committees within institutions do not include public representatives, and 41 percent of institutions with such committees do not require the evaluation of significant financial interests prior to final IRB review. In order for institutions to sustain credibility in the oversight and management of these processes and to maintain public trust and confidence, the AAMC feels that more public representation on standing conflicts of interest committees is needed to help safeguard research participants and institutional integrity.

To view the survey report, see http://www.aamc.org/members/coitf/coiresults2003.pdf.

Information about the AAMC is available at http://www.aamc.org.

**KA*

NIH PLACES BAN ON PRIVATE CONSULTING

In a memo to employees on September 24, 2004, Dr. Raynard Kington, Deputy Director of NIH announced a plan to impose a minimum one-year moratorium on private consulting by all NIH scientists.[1] The proposed ban is by far the most restrictive response yet to intense scrutiny the NIH has received from both the public and Congress over high consulting fees and lack of disclosure of consulting activities by NIH scientists. The primary concern is about conflict of interest, especially among top-level NIH scientists and supervisors who have consulting ties with biotech companies as well as NIH grant-making authority. Recommendations by a Blue Ribbon conflict of interest panel convened by NIH Director Elias Zerhouni earlier this year limited the amount of compensation that could be received and the number of hours per year an employee could devote to outside consulting. In August, NIH went beyond those recommendations to ban any NIH employee with even indirect authority over NIH grants from consulting and to even further cut possible compensation for those allowed to engage in consulting activities. At that time, NIH anticipated that the new oversight system would be fully active within six months.

The change to a complete ban on consulting is in part a response to the continuing disagreement between NIH and the Office of Government Ethics (OGE) over what actions the agency needs to take to resolve these issues.[2] However, it is also seated in concern over the depth of inadequacies in the system of oversight at NIH, as revealed by ongoing internal investigations. In his memo Dr. Kington wrote, "The moratorium will give [NIH] time to complete our review of specific cases, develop effective information systems to track outside activities, and develop more effective ethics training programs for staff before a final policy is put in place. . . [I]t is in the best interest of the NIH."[3] The proposal has been submitted to the OGE and will go into effect immediately upon approval. **KS*

[1] http://www.nih.gov/about/092404coi_policymemo.htm

[2] Weiss, Rick. "NIH Bans Collaboration with Outside Companies." *The Washington Post.* September 24, 2004.

[3] See note 1.

PRESIDENT'S COUNCIL ON BIOETHICS HOLDS EIGHTEENTH MEETING

On September 9 and 10, 2004, The President's Council on Bioethics met to discuss various topics, two of which were Neuroscience and the Law, and Understanding Aggressive Behavior through Neuroscience. Leon R. Kass, Chairman of the Council, introduced the topics by reflecting on the different ways science and the law treat violent behavior and aggression. Science tries to understand the mechanisms behind such behavior and plays a role in offering various explanations. The law, however, judges and holds people accountable for their behavior, with two outcomes: guilt or innocence. The significant question is to what extent can neuroscience influence the law by showing a defendant's lack of culpability despite commission of a criminal act? (Kass mentioned that neuroimaging data have already been used as evidence in an insanity defense). The guest speakers who assisted the Council in answering this question included Stephen J. Morse, Professor of Law and Professor of Psychology and Law in Psychiatry, University of Pennsylvania Law school, and Emil Coccaro, Clinical Neuroscience and Psychopharmacology Research Unit, University of Chicago. Dr. Morse addressed the extent of neuroscience's influence on the law; while Dr. Coccaro focused on the mechanistic explanations of aggressive behavior in individuals. Both speakers agreed that law, unlike mechanistic explanations, governs humans as intentional agents and judges actions, not brain activity. "We don't hold brain neurotransmitters responsible—we hold people responsible," said Morse.

Neuroscience does increase our understanding of human behavior, answer some causal questions, and may influence the verdict when enough significant evidence is provided. For now, however, with our existing knowledge, neuroscience can not dictate or determine law. **TJ*

UNION OF CONCERNED SCIENTISTS CONTINUES INVESTIGATION OF SCIENCE IN THE BUSH ADMINISTRATION

In July, the Union of Concerned Scientists (UCS) released a follow-up report to its February analysis of its claim that the Bush Administration (BA) misuses science for political ends. Endorsed by thousands of scientists, the report, *Scientific Integrity in Policy Making: Further Investigation of the Bush Administration's Misuse of Science*, describes incidents of the misuse of science according to two broad categories. Some examples of the incidents included in the report follow.

Undermining the Integrity of Scientific Analysis

The report cites several circumstances where scientific analysis within federal agencies has been suppressed or distorted. For example:

- As a result of a 1998 court ruling on mountaintop removal strip mining in Appalachia, the BA commissioned five federal and state agencies to conduct scientific studies of the issue in order to produce an environmental impact statement (EIS). While one stated purpose of the EIS was to suggest alternative options and their implications, records show that scientists were instructed by a Department of Interior official to shift the focus of the

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report away from alternatives. In addition, severity of the problem was downplayed in the final report by omitting words such as "significant" and "severe."

- In the case of deciding whether to approve an emergency contraceptive as an over-the-counter drug, a top FDA official acted contrary to FDA protocol by overruling the advice of scientific advisory panels and FDA staff, and denying approval for the drug to be sold without a prescription. The official defended his decision by claiming there was not enough evidence to prove the drug was safe for women aged 14-16. In fact, two science advisory panels had determined that the drug was equally safe for younger and older women.

Undermining the Integrity of Science Advisory Councils

The report also considers the use of political litmus tests as undermining the integrity of scientific advisory committees established by the federal government. An example is the use of political questioning when adding or renewing members of scientific advisory panels at NIH, the National Advisory Council for Human Genome Research, the National Institute on Drug Abuse, and the President's Council on Bioethics. Potential advisory committee members at these organizations were questioned by BA officials regarding their like or dislike of the President and their opinions on significantly politicized issues, such as stem cell research. Highly qualified experts were subsequently rejected for those advisory committees, according to the UCS, presumably based on positions not in line with those of the Bush Administration.

The full report can be found at http://www.ucsusa.org/global_environment/rsi/page.cfm?pageID=1449.

**LS*

RESOURCES

GENETIC POLICY AND LEGISLATION DATABASE LAUNCHED

If specific genetics-related policy and legislative documents continue to elude you, your search may be over thanks to a database recently launched on the Web by the US National Human Genome Research Institute (NHGRI). A click on www.genome.gov/LegislativeDatabase takes you just an index finger away from a clearinghouse of genetic policy, legislations, and useful links.

The database contains federal and state laws/statutes; federal legislative materials; and federal administrative and executive materials, including regulations, institutional policies, and executive orders. Perhaps more importantly, the database includes a summary – in layman's terms – of each document, making it possible to skip the legal particulars and get right to the point of on document's relevancy. Content currently focuses on the following subject areas: privacy of genetic information/confidentiality; informed consent; insurance and employment discrimination; genetic testing and counseling; and commercialization and patenting.

According to Francis Collins, NHGRI director, the database will be useful for everybody, "from academic researchers seeking to patent genetic technologies to average citizens trying to determine what protections exist in their states against genetic discrimination."[1]

Search tactics feature an interactive US map that highlights state-specific data, plus content type and source queries. Keyword searching is possible for words in document titles, but not those in their full text. The database contains only US policy and legislation. The addition of foreign content categories is expected this autumn. **AK*

[1] Campbell, Nick. "The NHGRI Policy and Legislation Database." *Nature Reviews Genetics,* September, 2004. Vol. 5, No. 9.

RCR RESOURCES NOW AVAILABLE ONLINE

The Office of Research Integrity has announced that the first 11 resources developed under the Responsible Conduct of Research (RCR) Resource Development Program are available on its website at http://ori.hhs.gov/html/rcreducation/ori_prod.asp. Some of the topics covered are:

- Online RCR Study Guide
- Online Research Ethics Course
- A Guidebook for Teaching Selected Responsible Conduct of Research Topics to a Culturally Diverse Trainee Group
- Welfare of Animals
- Conflicts of Interest
- Mentoring

The Resource Development Program was launched in 2002 to facilitate the development of RCR instructional materials for use by colleges and universities, hospitals, medical schools, scientific societies, and other scientific research organizations, thus relieving them of the need to create their own. A request for proposals is issued each year, usually in September. The next deadline for submission is February 25, 2005. More information on the RFP process is available at http://ori.hhs.gov/multimedia/acrobat/SOW%202005.pdf. **KS*

BEGINNING BIO-BUSINESS ETHICS:
A review of Margaret L. Eaton's *Ethics and the Business of Bioscience.*

by Brent Garland, AAAS

The term *bioscience* is general, encompassing many different fields—the agricultural, genomic, and bio-chemical, among them. The practitioners of bioscience come from companies large and small, and must be prepared to address a variety of ethics issues—some unique to their field or industry sector, some common to any scientist. For scientists, the need for ethics guidance has resulted in a small industry: companies provide training programs, and a variety of books on the ethics of science and research are available. The field of bioethics has produced a great deal of work on the ethics of human subjects research alone, as well as addressing other research concerns.

But the work of scientists does not exist in a vacuum, and much of the work of bioscientists is performed with an eye to commercial production and applications. Just like scientists, the businesspeople who seek to commercialize bioscience products have to consider the ethical and social impacts of their work.

In putting together the casebook *Ethics and the Business of Bioscience*, Margaret Eaton seeks to assist business students (and others) in considering bioscience business decisions from within an ethics framework. Eaton addresses a range of disciplines in the volume, considers companies that vary not only in product but also in size, and outlines a variety of ethical systems to consider. For its express purpose of facilitating "instruction in the effective business management of the ethical and social ramifications of commercializing new medical and biotechnology products," the book should serve remarkably well, though it may be of limited utility for others.

For the business student first approaching the study of ethics, the casebook is laid out in a very straightforward and sensible way. The first part of the book, and the shortest, makes the case for why one should study bioscience business ethics. Eaton notes the illustrative examples of nuclear power and genetically modified food crops as lessons on how the failure to consider social concerns can be dramatically damaging to business.

(**Resources** continued on page 7)

(**Resources** continued from page 6)

The second part of the book may well be of the greatest value for the business student or other people just beginning to consider business ethics issues. Part II opens with a brief overview of various ethics systems, and follows with examples of how ethics analysis might be applied. Though this section is unlikely to satisfy philosophers or other scholars of moral and ethical codes as sufficiently thorough, Eaton clearly lays out key ideas and principles from the most common systems of ethics, including utilitarianism, Kantian ethics, and modern theories of justice. For business students new to the subject of ethics, Eaton provides enough substance to power straightforward discussions of ethics issues.

The initial chapter in Part II is followed by a discussion of how the various ethical systems and frameworks might address the situation Monsanto faced regarding the labeling of dairy products containing recombinant bovine somatotropin (rbST), a synthetic growth hormone that stimulates milk production. The case study is presented in great detail, and a number of ethics analyses are applied, demonstrating how the choice of applicable ethics system can give rise to variations in what is identified as a problem, what might be considered as an appropriate response, and different standards for what constitutes acceptable resolution.

Eaton closes Part II of the book with two unsatisfactorily brief chapters offering primers on two complex topics: the regulation, testing and approval of medical devices and pharmaceutical products; and research ethics. The research ethics chapter addresses modern research ethics for both animals and people, and will only passably acquaint the reader with the history of modern ethics codes, including the Nuremberg Code, the Declaration of Helsinki, and the Belmont report.

The chapter on the regulation and approval of medical devices and pharmaceuticals is equally brief in laying out the stages and processes of Investigational New Drug applications, clinical trial phases, the role of Institutional Review Boards, and regulation of medical devices. While specific elements from both of the concluding chapters of this section are developed more fully in the final section of case studies, the chapters could have used more substance, and readers with an interest in either set of topics will need more information before they can begin to discuss either research ethics or drug/device approval and regulation with any degree of specificity.

Part III, the final section of the book, provides a series of case studies in the traditional format for discussion. It should be noted that the cases are somewhat more detailed than typical, in part because Eaton has provided a snapshot of the social context in which the cases occurred, such that the relevant ethics issues, social concerns, and stakeholders can be included in one's consideration of the case and business analysis. Eaton's case subjects are varied by company size, industry sector and the presentation of issues—all of which should help provide students with some range in their thinking about and discussion of the cases.

While the book has a great deal to offer, it should not be taken as a complete primer, but instead as an introductory text. The cases are drawn primarily from the 1990s, and so are relatively current, very instructive, and clearly presented. For those seeking to teach an introductory course on business ethics or to begin considering ethics issues arising specifically in the bioscience industry, this book offers an excellent single volume with which to begin.

Eaton, Margaret L., *Ethics and the Business of Bioscience*, Stanford, California: Stanford University Press, 2004. US$34.95 paper.

ANNOUNCEMENTS

Publication – The AAAS announces the publication of two volumes based on a workshop addressing the legal issues raised by increasingly sophisticated neuroscientific research techniques and discoveries. The workshop, a collaborative effort between the AAAS Scientific Freedom, Responsibility, and Law Program and the Dana Foundation, was held in September 2003. Both a summary and full report of the workshop are now available. The PDF version of the summary may be downloaded at http://www.aaas.org/spp/sfrl/projects/neuroscience/Summary.pdf. For print copies, visit http://www.press.uchicago.edu, or call 1-773-702-7000.

Conference – The Sixth Annual Conference on Ethics Across the Curriculum will be held October 14-16, 2004 at Oregon State University, Corvallis, Oregon. The conference theme is "Ethics and Organizations." More information on the conference and the Society for Ethics Across the Curriculum is available at http://www.rit.edu/~692awww/seac/conferences.OSU.html.

Conference – On October 14-15, 2004, the Center for Biomedical Ethics of the University of Virginia and ORI will sponsor a conference on Research Integrity and Financial Conflicts of Interest in Clinical Trials: Legal and Regulatory Requirements. For more information, visit http://ori.hhs.gov.

Forum – The U.S. Office for Human Research Protections and Indiana University will co-sponsor a one-day Research Community Forum on social, behavioral, education and humanities research with human subjects on October 20, 2004 at the Indiana Memorial Union in Bloomington, Indiana. For more information is http://www.indiana.edu/~ovpr/ohrp/index.html.

Conference – The Council of Science Editors is holding a two-day conference on "Conflict of Interest in Scientific Publications" at the Hyatt Lodge in Oak Brook, Illinois, from October 29-30, 2004. Visit http://ori.hhs.gov for more information.

Call for Papers — The Sixth Annual Conference of Computer Ethics: Philosophical Enquiry (CEPE2005) is scheduled for July 17-19, 2005 at the University of Twente, Enschede, The Netherlands. The theme is "Ethics of New Information Technologies." An abstract of between 1200 and 1400 words should be submitted by November 1, 2004. Selections will be made by January 15, 2005 and full papers are due May 1, 2005. More information is available at http://cepe2005.utwente.nl.

Conference – The Peru-U.S. Forum on Research Ethics is presenting a conference entitled "Collaborative Research with Human Participants in Latin America," December 2-3, 2004 at the Bethesda Regency Hyatt, Bethesda, Maryland. Registration ends November 1, 2004. For more information, visit http://www.hjf.org/events/index.html.

Conference – On November 12-14, 2004, the Office of Research Integrity, DHHS and the University of California, San Diego will present the 2004 Research Conference on Research Integrity at the Paradise Point Resort & Spa in San Diego, California. For more information, visit http://ethicsconference.ucsd.edu.

Conference – The Northwest Association for Biomedical Research (NAWBR) announces the Second Annual IRB Regional Education Conference, to be held on November 15, 2004 in Bellevue, Washington. For more information, contact Laurie Hassell of NAWBR at lhassell@nawbr.org.

Workshop – The American Academy of Religion is holding a one-day workshop on "Genes, Ethics, & Religion: A Blueprint Teaching" on November 19, 2004 in San Antonio, Texas. The workshop is to enable attendees to include material on genetic ethics in course offerings and curricula. Visit www.aarweb.org for more information.

(**Announcements** continued on page 8)

Conference – A two-day conference on "Stem Cells: Saving Lives or Crossing Lines" will be held on November 20-21, 2004 at Rice University. The conference is intended to bring together policy makers, ethicists, business leaders, science journalists, and scientists to discuss human embryonic stem cell research in the United States. For more information, contact Kirstin Matthews at the James A. Baker III Institute of Public Policy at Rice University, krwm@rice.edu.

Request for Proposals – The Department of Health and Human Services is accepting proposals for research on societal, organizational, group, and individual factors that affect integrity in research, with relevance to biomedical, behavioral health and health services research. For more information, including instructions and where to direct inquiries, visit http://grants1.nih.gov/grants/rfa-files/RFA-NS-05-003-html.

Conference – On December 2-3, 2004, a conference on "Developing Policy on Institutional Conflict of Interest: Maintaining Public Confidence" will be held at the University of Nevada, Las Vegas. Co-sponsors of the conference include AAAS, AAMC, AAU, DHHS, and NASULGC. Information in the conference, including agenda and registration, is located at http://www.unlv.edu/Research/ecoDev_ICOI.html.

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